

Hearing Date: July 23, 2020 at 2:00 p.m. (ET)
Objection Deadline: July 16, 2020 at 4:00 p.m. (ET)

IN THE UNITED STATES BANKRUPTCY COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

In re

PURDUE PHARMA L.P., et al.,

Debtors.¹

Chapter 11
Case No. 19-23649 (RDD)
Administratively Consolidated

Related Docket No. 1330

**SUPPLEMENT TO HOSPITAL CLAIMANTS' MOTION PURSUANT TO FED.
BANKR. P. 9014 AND 7023 FOR AN ORDER MAKING FED. R. CIV. P. 23
APPLICABLE TO THESE PROCEEDINGS, PERMITTING THEM TO FILE A CLASS
PROOF OF CLAIM AND GRANTING RELATED RELIEF**

The Hospital Claimants,² on behalf of themselves and a proposed class of similarly situated persons, by and through their undersigned counsel, hereby submit this supplemental submission for the purpose of providing the Court with the authorities and sources cited in the

¹The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF LP (0495), SVC Pharma LP (5717), and SVC Pharma Inc. (4014).

²As used herein, the "Hospital Claimants" or "Hospitals" are: Infirmary Health Hospitals, Inc., Mobile, Alabama; St. Vincent Charity Medical Center (at times d/b/a Rosary Hall), Cleveland, Ohio; Southwest Mississippi Regional Medical Center, McComb, Mississippi; and Monroe County Healthcare Authority, d/b/a Monroe County Hospital, Monroeville, Alabama.

Hospital Claimants Motion [Dkt. No. 1330] that may not be readily available to the Court.

Dated: July 16, 2020

Respectfully submitted,

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Exhibit 1

Bradburn Parent/Teacher Store, Inc. v. 3M, No. Civ. A. 02-7676,
2004 WL 1842987 (E.D. Pa. Aug. 18, 2004)

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 KeyCite Yellow Flag - Negative Treatment
Distinguished by [American Seed Co., Inc. v. Monsanto Co.](#), D.Del., November 13, 2006

2004 WL 1842987
United States District Court,
E.D. Pennsylvania.

BRADBURN PARENT/TEACHER STORE, INC.

v.

3M (MINNESOTA MINING AND
MANUFACTURING COMPANY)

No. Civ.A.02-7676.

|
Aug. 18, 2004.

Attorneys and Law Firms

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MEMORANDUM

[PADOVA](#), J.

*1 Following the Court's denial of Plaintiff's original Motion for Class Certification, Plaintiff has filed a Renewed Motion for Class Certification seeking certification of a modified class. Plaintiff asserts that certification of this modified class will not trigger the

same infirmities which caused the Court to deny Plaintiff's original Motion for Class Certification. Defendant opposes certification of the proposed modified class. For the reasons that follow, the Court will grant Plaintiff's Renewed Motion for Class Certification, and will certify Plaintiff's proposed modified class, subject to the conditions which are set forth in the accompanying order.

I. BACKGROUND

The conduct of Defendant which forms the basis of this lawsuit was the subject of a prior lawsuit in this Court, *LePage's, Inc. v. 3M*, Civ. A. No. 97-3983. In that suit, a competing supplier of transparent tape, LePage's, Inc. ("LePage's"), sued Defendant alleging, *inter alia*, unlawful maintenance of monopoly power in violation of Section 2 of the Sherman Act,  15 U.S.C. § 2. After a nine-week trial, the jury found in favor of LePage's on its unlawful maintenance of monopoly power claim, and awarded damages of \$22,828,899.00, which were subsequently trebled to \$68,486,697.00. See *LePage's, Inc. v. 3M*, Civ. A. No. 97-3983, 2000 U.S. Dist. Lexis 3087 (E.D.Pa. Mar. 14, 2000). This Court subsequently denied Defendant's Motion for Judgment as a Matter of Law with respect to this claim. See *id.* A panel of the United States Court of Appeals for the Third Circuit ("Third Circuit") initially reversed this Court's Order upholding the jury's verdict and directed this Court to enter judgment for Defendant on LePage's' unlawful maintenance of monopoly power claim.  *LePage's, Inc. v. 3M*, 277 F.3d 365 (3d Cir.2002) ("LePage's I"). Upon rehearing *en banc*, the Third Circuit vacated the panel decision and reinstated the jury verdict against Defendant on LePage's' unlawful maintenance of monopoly power claim.  *LePage's, Inc. v. 3M*, 324 F.3d 141 (3d Cir.2003) ("LePage's II"), cert. denied *3M Co. v. LePage's, Inc.*, 542 U.S. 953, 124 S.Ct. 2932, 159 L.Ed.2d 835 (2004).

The Complaint in this matter alleges one count of monopolization in violation of  Section 2 of the Sherman Act,  15 U.S.C. § 2. The Complaint alleges that Defendant unlawfully maintained its monopoly in the transparent tape market through its bundled rebate programs¹ and through exclusive dealing arrangements

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with various retailers. The Complaint asserts that, as a result of Defendant's conduct, Plaintiff and other members of the proposed Class have "suffered antitrust injury." (Compl. ¶ 27). The damages period in this case runs from October 2, 1998 until the present. (Compl. ¶ 2). Plaintiff seeks declaratory relief, permanent injunctive relief, treble compensatory damages, attorney's fees, costs and interest. (See Compl. ¶¶ A-F).

II. LEGAL STANDARD

Before a class may be certified pursuant to [Federal Rule of Civil Procedure 23](#), the plaintiff "must establish that all four requisites of [Rule 23\(a\)](#) and at least one part of [Rule 23\(b\)](#) are met." [Baby Neil v. Casey](#), 43 F.3d 48, 55 (3d Cir.1994). The requirements of [Rule 23\(a\)](#) are as follows:

- *[2](#) (1) Numerosity (a "class [so large] that joinder of all members is impracticable");
- (2) commonality ("questions of law or fact common to the class");
- (3) Typicality (named parties' claims or defenses are "typical of ... the class"); and
- (4) adequacy of representation (representatives "will fairly and adequately protect the interests of the class").

[Amchem Prods. v. Windsor](#), 521 U.S. 591, 613, 117 S.Ct. 2231, 138 L.Ed.2d 689 (1997) (quoting [Fed.R.Civ.P. 23\(a\)](#)). The purpose of these procedural requirements is "so that the court can assure, to the greatest extent possible, that the actions are prosecuted on behalf of the actual class members in a way that makes it fair to bind their interests." [Newton v. Merrill, Lynch, Pierce, Fenner & Smith](#), 259 F.3d 154, 182 n. 27 (3d Cir.2001).

A plaintiff must also satisfy the requirements found in one of the three sections of [Rule 23\(b\)](#). Plaintiff asserts that it satisfies the requirements of [Rule 23\(b\)\(3\)](#). The prerequisites for certification under [Rule 23\(b\)\(3\)](#) are as follows:

To qualify for certification under [Rule 23\(b\)\(3\)](#), a class must meet two requirements beyond the [Rule 23\(a\)](#) prerequisites: Common questions must "predominate over any questions affecting only individual members"; and class resolution must be "superior to other available methods for the fair and efficient adjudication of the controversy."

[Amchem Prods.](#), 521 U.S. at 615.

Class certification rests within the District Court's discretion. [Eisenberg v. Gaqnon](#), 766 F.2d 770, 785 (3d Cir.1985). In determining whether the class should be certified, the Court examines only the requirements of [Rule 23](#) and does not look at whether the Plaintiffs will prevail on the merits. [Eisen v. Carlisle & Jacqueline](#), 417 U.S. 156, 177-78, 94 S.Ct. 2140, 40 L.Ed.2d 732 (1973) ("In determining the propriety of a class action, the question is not whether the plaintiff or plaintiffs have stated a cause of action or will prevail on the merits, but rather whether the requirements of [Rule 23](#) are met.") (quoting [Miller v. Mackey Int'l](#), 452 F.2d 424, 427 (5th Cir.1971)). However, the Court must also "carefully examine the factual and legal allegations" made in the Complaint. [Barnes v. American Tobacco Co.](#), 161 F.3d 127, 140 (3d Cir.1998).

III. PRIOR OPINION

In its first Motion for Class Certification, Plaintiff sought certification of:

a class of persons ... directly purchasing from the Defendant invisible and transparent tape between October 2, 1998 and the present.

(Compl. ¶ 10.) In an Order and Memorandum dated March 1, 2004, this Court denied Plaintiff's Motion. See [Bradburn Parent/Teacher Store v. 3M](#), No. 02-7676, 2004 WL 414047 (E.D.Pa. Mar.1, 2004). The Court specifically found that Plaintiff failed to satisfy the

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requirements of  [Federal Rule of Civil Procedure 23\(a\)\(4\)](#), in that Plaintiff failed to show that it could adequately protect the interests of all of the proposed class members. Specifically, the Court found that Plaintiff's position as a sole purchaser of 3M branded transparent tape resulted in a conflict of interest between Plaintiff and those class members who purchased "private label" tape.² Those members of the proposed class who purchased significant quantities of private label tape, the Court found, would likely be interested in pursuing a "lost profits" theory of damages, and would accordingly seek to present evidence that maximized a shift in market share from 3M branded to private label tape in the absence of 3M's anti-competitive conduct. Plaintiff, by contrast, was solely pursuing an overcharge theory of damages, and therefore would attempt to demonstrate that the price of 3M branded tape would have fallen in the absence of 3M's anti-competitive conduct. The court found that these two competing positions resulted in an apparent and imminent conflict among members of the proposed class. The Court reserved decision on the question of whether Plaintiff's proposed class satisfied the requirements of  [Federal Rule of Civil Procedure 23\(b\)\(3\)](#).

IV. DISCUSSION

*3 Plaintiff now seeks certification of the following modified class:

All persons who directly purchased invisible or transparent tape from 3M Company between October 2, 1998 and the present, who have not purchased, for resale under the class member's own label, any "private label" invisible or transparent tape from 3M Company or any of 3M Company's competitors at any time from October 2, 1988 to the present.

(See Docket # 141). Plaintiff proposes to pursue an overcharge theory of damages for the proposed class, and seeks to recover the difference between the price that class members paid for transparent tape during the

damages period in this case and the price that they would have paid in a but-for world absent 3M's anti-competitive conduct. Plaintiff argues that, because all purchasers of private label tape from 1988 until the present are excluded from the modified class, the conflicts that caused the Court to deny class certification in the first instance have now been eliminated. Plaintiff further asserts that the proposed modified class satisfies all of the other requirements of  [Rule 23](#).

A. Numerosity and Commonality

"Generally if the named plaintiff demonstrates that the potential number of plaintiffs exceeds 40, the [numerosity] prong of  [Rule 23\(a\)](#) has been met."

 [Stewart v. Abraham](#), 275 F.3d 220, 226-27 (3d Cir.2001) (citation omitted). Plaintiff asserts that the proposed modified class exceeds 200 members. (Pl's Renewed Mot. Class Cert. at 11.) While Defendant contests the methodology that Plaintiff has used to arrive at this figure, Defendant never specifically contests Plaintiff's assertion that the modified class satisfies the numerosity requirement. Moreover, Defendant argues that Plaintiff's methodology for determining the number of members of the proposed class is flawed because Plaintiff utilized 3M customer lists which did not include all of 3M's customers. (Def's Opp. Mem. at 23.) Accordingly, if Defendant's argument is correct, Plaintiff has likely underestimated the number of members of the proposed class. The Court therefore finds that the class is so large that the joinder of all members is impracticable.

 [Fed.R.Civ.P. 23\(a\)\(1\)](#). Accordingly, the numerosity requirement is satisfied.

"The commonality requirement will be satisfied if the named plaintiffs share at least one question of fact or law with the grievances of the prospective class."  [Baby Neil](#), 43 F.3d at 56. Defendant has not contested commonality, and the Court finds that numerous common questions of law and fact are present in this case. The Court, therefore, finds that the commonality requirement is satisfied.

B. Adequacy of Representation

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"The adequacy of the class representative is dependant on satisfying two factors: 1) that the plaintiffs' attorney is competent to conduct a class action; and 2) that the class representatives do not have interests antagonistic to the interests of the class." *In re Linerboard Antitrust Litig.*, 203 F.R.D. 197, 207 (E.D.Pa.2001) (citations omitted). Defendant does not challenge the ability of Plaintiff's law firm to litigate this class action. Rather, Defendant continues to assert that Plaintiff is not an adequate class representative because it has interests which are in direct conflict with the interests of many of the potential class members. "The adequacy inquiry under Rule 23(a)(4) serves to uncover conflicts of interest between named parties and the class they seek to represent." *Amchem Prods.*, 521 U.S. at 625. Thus, "a class representative must be part of the class and 'possess the same interest and suffer the same injury' as the class members." *East Tex. Motor Freight Sys. v. Rodriguez*, 431 U.S. 395, 403, 97 S.Ct. 1891, 52 L.Ed.2d 453 (1977) (quoting *Schlesinger v. Reservists Committee to Stop the War*, 418 U.S. 208, 216 (1974)); see also *Georgine v. Amchem Prods., Inc.*, 83 F.3d 610, 630 (3d Cir.1996), aff'd sub nom. *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 117 S.Ct. 2231, 138 L.Ed.2d 689 (1997) (finding class representative inadequate where proposed settlement made "important judgments on how recovery is to be allocated among different kinds of plaintiffs, decisions that necessarily favor some claimants over others.") (emphasis in original).

*4 Consequently, the adequacy of representation requirement is not satisfied where "the named representative's interest in maximizing its own recovery provides a strong incentive to minimize the recovery of other class members." *Yeager's Fuel v. Pennsylvania Power & Light Co.*, 162 F.R.D. 471, 478 (E.D.Pa.1995) ("Yeager's Fuel II"). For example, in *Yeager's Fuel II*, this Court refused to certify a class of competing retail fuel dealers who competed with each other in a limited market for retail fuel sales, and who argued that they lost business as a result of the defendant's anti-competitive conduct. *Id.* The Court noted that "the named representative's interest in maximizing its own recovery provides a strong incentive to minimize the recovery of other class members, which may be accomplished by showing that any business lost by other class members, as opposed to itself, was caused by some factor independent of the defendant's anti-competitive conduct." *Id.*; see also *Pennsylvania Dental Assn. v. Medical Service Assn.*

of Pennsylvania, 745 F.2d 248, 263 (3d Cir.1984)(affirming the district court's decision to certify class containing dentists who did and did not participate in a challenged dental fee program, because of "inherent conflicts" between the two groups); *Glictronix Corp. v. AT & T Co.*, 603 F.Supp. 552, 586 (D.N.J.1994) ("cases in the Third Circuit consistently support the view that where the class members are competitors in a limited market, the named plaintiff's attempts to maximize its damage recovery will conflict with the interests of the other class members and class certification should be denied.")

However, "[M]ost courts hold that [a] conflict [between class members] must be more than merely speculative or hypothetical" before a named representative can be deemed inadequate. 5 James Wm. Moore, et al., *Moore's Federal Practice* 23.25 [4][b][ii] (3d ed.2003); see also *Blackie v. Barrack*, 524 F.2d 891, 909 (9th Cir.1975) ("[C]ourts have generally declined to consider conflicts, particularly as they regard damages, sufficient to defeat class action status at the outset unless the conflict is apparent, imminent, and on an issue at the very heart of the suit."); *Audrey v. Federal Kemper Ins. Co.*, 142 F.R.D. 105, 111-13 (E.D.Pa.1992) (proposed class representatives held to be adequate where plaintiffs had presented persuasive evidence that all class members had been injured by defendant's conduct, and defendant had failed to present any evidence of potential antagonism between class members); *In re South Central States Bakery Prods. Antitrust Litig.*, 86 F.R.D. 407, 418 (M.D.La.1980) ("A naked allegation of antagonism cannot defeat class certification; there must be an actual showing of a real probability of a potential conflict which goes to the subject matter of the suit.").

1. Premium brand vs. second tier brand purchasers

Defendant maintains that there are conflicts of interest between members of the proposed class, rendering class certification inappropriate. Specifically, Defendant argues that the market includes purchasers of two types of transparent tape products from 3M, premium tape, sold under the name "Scotch Magic", and "second tier" brand tapes, sold under the name "Scotch" or "Highland." According to Defendant, premium brand tape and second tier tapes occupy different segments of the transparent tape market. Because of this, the prices of premium and

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second tier brand tapes would not have responded in a similar fashion in response to any increased competition that might have occurred in a world absent 3M's anti-competitive conduct. In support of this theory, Defendant has presented the expert testimony of Dr. Daniel Rubinfeld, who previously testified on behalf of Defendant in connection with its opposition to Plaintiff's first motion for class certification. According to Dr. Rubinfeld, because of "differences between consumers in terms of their relative attachment to a brand," prices for premium brand products do not always fall in response to competition from private label products and other low cost substitutes. (4/15/04 Rubinfeld Decl. ¶ 9). Rather, it is sometimes the case that a company will respond to competition by cutting the price of its second tier brand in response to competition, while maintaining the same price, or even raising the price, of the premium brand product. (4/15/04 Rubinfeld Decl. ¶ 10). Dr. Rubinfeld describes a second tier brand which is utilized by a company to provide an alternative to lower priced products provided by competitors as a "fighting brand." (4/15/04 Rubinfeld Decl. ¶ 8.) According to Dr. Rubinfeld, the reason for this phenomenon is that, in some markets, "demand consists of two segments: brand-loyal purchasers who value the premium branded product and price sensitive purchasers for whom the fighting brand and the private label product are close substitutes." (4/15/04 Rubinfeld Decl. ¶ 10). Dr. Rubinfeld labels this underlying phenomenon market segmentation.

*5 According to Dr. Rubinfeld, his preliminary research suggests that 3M utilized its second tier tapes, such as Highland tape, as fighting brands to respond to competition from other sources and to provide an alternative for those customers seeking a lower-priced tape. (5/17/04 Rubinfeld Decl. ¶¶ 9-10). By contrast, according to Dr. Rubinfeld's research, 3M generally did not respond to competitive threats by lowering the price of its premium Scotch Magic Tape. (*Id.*) According to Dr. Rubinfeld, this provides evidence that the market for transparent tape is segmented, and that 3M would, therefore, have lowered the price of its second tier tapes, but not its premium tape, in response to competition in a world absent 3M's anti-competitive conduct. (*Id.*)

3M argues that the possibility that the transparent tape market is segmented in turn creates an imminent and apparent conflict between members of the proposed class. 3M notes that, if the market for transparent tape were segmented, the price of premium Scotch Magic tape would fall insignificantly, if at all, in response to

competition. Accordingly, members of proposed class who purchased mainly premium Scotch Magic tape will have an incentive to reject the market segmentation theory described by Dr. Rubinfeld. These class members would instead wish to argue that the prices of both premium and second tier tapes would have fallen in a similar fashion, in order to maximize the amount of their recovery in this case. Plaintiff is pursuing this theory of damages, which Plaintiff labels a "one market" theory, and is seeking to recover overcharge damages on its purchases of both premium and second tier 3M transparent tape. (See Pl.'s Reply Mem. at 2-3.) By contrast, according to 3M, those class members who mainly or only purchased second tier transparent tape would have an incentive to pursue the market segmentation theory, because it is possible that under such a theory the price decrease in second tier tapes would be larger if the market were segmented than if the prices of premium and second tier tapes responded to competition in a similar fashion. (5/17/04 Rubinfeld Decl. ¶ 14.)

Plaintiff argues that the conflict described by 3M is illusory, as it is not at all clear that those class members who purchased primarily second tier transparent tape would be harmed by the pursuit of a one market theory. Indeed, according to Plaintiff's expert, Dr. Morton Kamien, the amount of overcharge damages based upon purchases of second tier tape would be no different under a market segmentation theory than it would be under a one market theory. (5/6/04 Kamien Decl. ¶¶ 9-11.) This is because, according to Dr. Kamien, the price of second tier tape would be lowered the same amount in response to competition regardless of whether 3M chose to lower the price of both premium brand tape and second tier tape in response to competition, as would be the case under a one market theory, or chose only to lower the price of second tier tape, as would be the case under a market segmentation theory. (*Id.*) Dr. Kamien testified that "[3M] would have at least as much incentive to reduce [second tier tape prices] if the entire market is price sensitive as it would have if the market is 'segmented' (that is, if only part of the market is price-sensitive)." (5/6/04 Kamien Decl. ¶ 10.) Moreover, Dr. Rubinfeld does not explain, and it is not immediately apparent to the Court, why the amount of the price cut on 3M's second tier tape would necessarily vary inversely with the amount of the price cut made to 3M's premium tape under a "one market" theory. Indeed, while Dr. Rubinfeld certainly argues that such a phenomenon is possible, Dr. Rubinfeld does not appear to argue that such a phenomenon would be likely to occur in this case. Dr. Rubinfeld merely states that

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*6 it may be that the decrease in the price of a fighting brand product such as Highland could be larger under a segmentation theory than it could be under what Plaintiff labels a “one market” theory. In other words, by pursuing a segmentation theory, a class member might credibly argue for a larger overcharge on Highland purchases than they could by pursuing a “one market” theory.

(5/17/04 Rubinfeld Decl. ¶ 14.)³ Accordingly, the Court finds that the mere possibility that the price decrease in second tier tape could be larger under a segmentation theory than under a one market theory does not create an apparent and imminent conflict of interest between members of the proposed class.⁴

3M further argues that, based upon the evidence presented in the *LePage*'s trial and during preliminary discovery related to the instant motion for class certification, it will be easier for the Plaintiff class to pursue damages based upon overcharges on second tier tape than it will be to pursue damages based upon overcharges on 3M's premium tape. 3M relies upon documents which it claims strongly suggest that 3M responded to competitive threats by lowering the price of second tier tapes, and not by lowering the price of Scotch Magic tape. According to 3M, its analysis of 82 “meeting competition” forms demonstrates that, in all but a handful of the 82 instances, 3M responded to competitive threats by lowering the price of its second tier tapes, as opposed to its premium tape. (5/17/04 Rubinfeld Decl. ¶¶ 9-10.) According to 3M, the “uphill battle” faced by class members who primarily or only purchased 3M's premium tape, and therefore must pursue overcharge damages based upon sales of 3M's premium tape, can be avoided by class members who primarily or only purchased 3M's second tier tapes, and who can therefore pursue overcharge damages based solely upon their purchases of second tier tapes. Thus, according to Dr. Rubinfeld,

in the face of evidence such as that contained in the meeting competition forms, it would be easier to credibly argue that the

prices of Highland and lower-end Scotch tapes would have declined significantly than it will be to credibly argue that Scotch Magic prices declined significantly. Thus, by attempting to claim significant overcharges on Scotch Magic purchases, Highland purchasers may damage the credibility of their arguments with respect to Highland purchases.

(5/17/04 Rubinfeld Decl. at ¶ 14.)

According to 3M, therefore, the mere risk that the theory proposed by Plaintiff will be less well received than a competing theory which could be put forward by other potential class members is sufficient for the Court to find the existence of an imminent and apparent potential conflict. The Court rejects this argument. In order to determine whether Plaintiff's pursuit of overcharge damages on both premium and second tier transparent tape would work to the detriment of other class members by “damag[ing] the credibility” of their case, the Court would be required to evaluate the underlying viability of Plaintiff's one market theory. Accordingly, Defendant's argument is, at bottom, an attack on the merits of Plaintiff's “one market” theory of damages. However, as will be discussed, *infra*, a court may not weigh conflicting expert testimony or economic theories, and may not determine which of two competing theories is more appropriately applied to the facts of the instant case, at the class certification stage. See  *In re Visa Check/Master Money Antitrust Litig.*, 280 F.3d at 135.⁵

*7 The alleged conflicts identified by 3M in its opposition to certification of the modified class are fundamentally different than the previously identified conflicts between members of the original proposed class. In its prior Memorandum denying certification of the original class, this Court found that an imminent and apparent conflict existed between those class members who purchased private label tape and those class members who only purchased 3M branded tape. That conflict was based upon the fact that Plaintiff's proposed overcharge theory of damages, which was necessarily predicated on the assumption that prices for 3M branded tape would fall in response to competition, ran a serious risk of minimizing the recovery of those class members who would wish to pursue a lost profits theory of damages based upon a shift

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in sales to private label tape, and who would therefore wish to argue that the price of 3M branded tape would have risen or stayed the same in response to competition.

See [2004 WL 414047](#), at *4. By contrast, in this case, there is nothing in the record to indicate that Plaintiff's one market theory will work to the detriment of purchasers of second tier tape, with the exception of Dr. Rubinfeld's unsupported assertion that the price decrease of a second tier product "could be larger" under a market segmentation theory (5/17/04 Rubinfeld Decl. ¶ 14.), an assertion that Dr. Kamien categorically rejects.

The Court further notes that Plaintiff itself purchased significant quantities of second tier tape. Indeed, according to Dr. Rubinfeld, 3M's own expert, 30% of Bradburn's tape purchases were purchases of Highland Tape. (4/15/04 Rubinfeld Decl. ¶ 16.) Thus, if the evidence were to demonstrate that the one market theory could not be feasibly applied to the market for transparent tape, and that the market segmentation theory could properly be applied to this market, there is no reason to believe that Plaintiff would simply ignore the market segmentation theory and instead continue to pursue a one market theory. Furthermore, if the one market theory proved to provide a poor description of the market for transparent tape, and if Plaintiff nevertheless continued to pursue this theory, class members would have the right to opt out of the class pursuant to [Federal Rule of Civil Procedure 23\(c\)\(2\)](#).⁶

[02-7676, 2000 WL 34003597](#), at *4 (E.D.Pa. Jul.25, 2003). Accordingly, at this point in the proceedings, the Court cannot determine whether there are any members of the proposed class who have benefitted from 3M's anti-competitive conduct, and the fact that there may be class members who received the challenged rebates is not a sufficient basis on which to deny class certification.

3. Breaches of Fiduciary Duty by Bradburn's Corporate Executives

*8 3M also argues that Plaintiff is an inadequate representative of the proposed class by virtue of alleged prior breaches of fiduciary duty by its corporate officers. 3M asserts that this prior conduct establishes that Plaintiff's executive officers do not possess the honesty and integrity required of a class representative. Specifically, Defendant alleges that Elizabeth Parkinson, who is currently Chief Executive Officer of Bradburn, and Brad Parkinson, who is Elizabeth Parkinson's son and currently owns 90% of the company, engaged in a practice of charging personal expenses on company credit cards. Mr. Parkinson was also accused of improperly taking out personal loans from the company. (Def's Mot. Ex. N., Arthur Larson Dep. at 20). When the allegedly improper credit card charges were discovered, other corporate officers of Bradburn demanded that Elizabeth and Brad Parkinson repay these charges. However, according to Arthur Larson, who was until recently also a corporate officer of Bradburn, while Elizabeth Parkinson did pay back all of her disputed charges, Brad Parkinson only paid back some of his disputed charges. (Larson Dep. at 154). Arthur Larson, along with his brother, David, subsequently filed an action to dissolve Bradburn as a corporate entity. This suit, which was filed in Missouri state court in the year 2001, was eventually settled by an agreement that Bradburn would sell off its catalogue business, while Brad and Elizabeth Parkinson would retain ownership and control of the remaining assets. (See Pl's Mot. Class Cert. Ex. 21.) Importantly, there is no evidence that the court considering the Larsons' action for dissolution of Bradburn, or any other court, ever made a determination that either Brad or Elizabeth Parkinson engaged in any wrongdoing. Moreover, while Brad and Elizabeth Parkinson's improper expenses and loans were a factor in the Larsons' decision to dissolve the company, the decision was also based upon various disagreements between the Parkinsons and the Larsons concerning the management of the

2. Beneficiaries of Bundled Rebates

Defendant also argues that Plaintiff cannot represent a class containing members who benefitted from 3M's anti-competitive conduct which formed the basis of the LePage's lawsuit (i.e., the bundled rebates). "A class cannot be certified when its members have opposing interests or when it consists of members who benefit from the same acts alleged to be harmful to other members of the class." [Pickett v. Iowa Beef Processors](#), 209 F.3d 1276, 1280 (11th Cir.2000) (citations omitted). Defendant argues that the rebate recipients may have a strong interest in maintaining the position that 3M's conduct was lawful, and therefore will oppose this suit. However, as the Court has previously noted, Plaintiff contends that every member of the proposed class paid too much for 3M branded tape, regardless of whether they received any bundled rebates from 3M. See [Bradburn v. 3M](#), No.

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company which do not call the Parkinsons' integrity into question. (See Def's Opp. Mem. Ex. T.)

There are no bright line rules to follow in determining whether a proposed class representative has sufficient integrity to fulfill his role. However, courts which have found that a class representative lacks the requisite integrity to serve as class representative have been faced with conduct significantly more serious than the conduct faced here. See *Folding Cartons v. American Can Co.*, 79 F.R.D. 698, 703 (N.D.Ill.1978) (proposed named plaintiff who had been found by court in prior, unrelated action to have engaged in deliberately deceptive behavior held to be inadequate representative.) Courts have generally been unwilling to find a representative inadequate based upon behavior which is not related, in time or subject matter, to the case at hand. See *Koppel v. 4897 Corp.*, 191 F.R.D. 360, 368 (S.D.N.Y.2000) (fact that named plaintiff filed frivolous lawsuit some fifteen years earlier attempting to extort money from the defendant was "too unsubstantiated and attenuated, in time and subject matter, to seriously call into question his ability to pursue this litigation and protect the interests of the proposed class."); *Jane B. v. New York City Dept. Of Social Serv.*, 117 F.R.D. 64, 71 (S.D.N.Y.1987) ("The inquiry, then, into the representatives' personal qualities is not an examination into their moral righteousness, but rather an inquiry directed at improper or questionable conduct arising out of or touching upon the very prosecution of the lawsuit."); *Randle v. Spectran*, 129 F.R.D. 386, 392 (D.Mass.1988) (proposed representative who had been indicted for arson more than ten years prior to the suit, and had admitted during his deposition that he had filed no tax return for two separate years, not disqualified from serving as representative.)⁷

*9 The prior conduct of Elizabeth and Brad Parkinson that Defendant has identified does not indicate to the Court they lack the honesty and integrity required of class representatives. First, both Elizabeth and Brad Parkinson dispute the contention that any of the questionable credit card charges they made were indeed improper,⁸ and no court has ever so found. Indeed, according to Ms. Parkinson, she repaid the credit card charges to the company in an effort to keep peace with the other directors, some of whom are apparently members of her family, and not because she believed that she had engaged in any wrongdoing. (8/13/03 N.T. at 49.) Thus, absent a finding from any judicial body that these charges were fraudulent or otherwise violated the law, the Court would be forced to engage in a thorough analysis of both the

underlying circumstances of each of the disputed charges as well as of Missouri corporations law in order to determine whether any of these charges were indeed improper. The Court declines to engage in such an analysis, which would waste valuable judicial resources and unnecessarily delay this litigation.

Furthermore, while Ms. Parkinson does admit that the personal loans she received from the company were improper, Ms. Parkinson noted during her hearing testimony that these loans were taken out in response to a family emergency, and that when she took out the loans she had every intention of repaying them at a later date, which she eventually did. (8/13/03 N.T. at 61-62). Lastly, it should be noted that Arthur Larson, one of the persons who accused Ms. Parkinson of impropriety, still asserts that he believes that she is an honest person. (Pl's Reply Mem. Ex. 6, 2nd Larson Dep. at 95-99.) Accordingly, the Court finds that Brad and Elizabeth Parkinson possess the requisite honesty and integrity to serve as class representatives.

4. *The relationship between Brad Parkinson and Terry Parkinson*

3M also argues that Bradburn is an inadequate class representative by virtue of the fact that Brad Parkinson, who owns 90% of the company, is the husband of one of the attorneys representing Bradburn, Terry Parkinson, and further that Elizabeth Parkinson, who is currently an officer at the company, is Brad Parkinson's mother and the mother-in-law of Terry Parkinson. Terry Parkinson works for the law firm of Welsh and Hubble, and Plaintiff admits that Ms. Parkinson has a financial interest in any fees earned by the firm. (8/13/03 N.T. at 21.) Defendant cites to a long line of cases which have refused to certify a class representative who was a close relative of one of the class counsel. See *Zlotnick v. Tie Communications, Inc.*, 123 F.R.D. 189, 193-94 (E.D.Pa.1988); *In re Microsoft Corp. Antitrust Litig.*, 214 F.R.D. 371, 374-75 (D.Md.2003). The rationale behind these courts' determinations is the obvious risk that the class representative's interests will be aligned with the interests of the representatives' attorneys, and not with the interests of the other members of the class.

*10 However, the mere presence of a familial relationship between a class representative and class counsel is not

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generally sufficient in itself for the court to find that the class representative is inadequate. Rather, courts generally will only find inadequacy if other factors which call into question a class representative's loyalty to other members of the class are present. For example, in *Zlotnick*, the court refused to certify the class because, in addition to the fact that the proposed class representative was the father of class counsel, the father admitted during his deposition that he knew nothing about the case and deferred to his son's decisions on the matter.  123 F.R.D. at 193-94.

Most courts have also found a class representative inadequate where that class representative maintained a financial interest in an award of attorney's fees to the class counsel. See  *Sussman v. Lincoln American Corp.*, 561 F.2d 86 (7th Cir.1977);  *Fischer v. Int'l Tel. & Tel. Corp.*, 72 F.R.D. 170, 174 (E.D.N.Y.1976).⁹

Defendant has pointed to no evidence that Elizabeth Parkinson is a mere pawn of her daughter-in-law in this litigation, or that Elizabeth Parkinson will directly benefit from any award of attorney's fees to Terry Parkinson or her law firm, Welsh and Hubble, P.C. As the spouse of Terry Parkinson, however, it is highly likely that Brad Parkinson would directly benefit from any benefit that Terry Parkinson would receive by virtue of her representation of Bradburn in this case. Plaintiff vehemently argues, however, that Brad Parkinson's 90% ownership of Bradburn should not play a factor in the Court's analysis, because only Bradburn Parent Teacher Store, Inc., and not Brad Parkinson himself, seeks to be appointed class representative. Thus, according to Plaintiff, unless and until Defendant is able to "pierce the corporate veil" of Bradburn and establish that Bradburn is a mere "alter ego" of Brad Parkinson himself, Mr. Parkinson's stake in Bradburn is essentially irrelevant. The Court disagrees. Plaintiff has not presented, and the Court has not found, any authority which supports Plaintiff's proposition that majority ownership of a company is irrelevant in determining potential conflicts of interest between class representatives and other class members. Moreover, the Court finds that there is a substantial risk that Brad Parkinson, who is a 90% owner of the company and the son of the Chief Executive Officer, could have substantial influence over the company's decision-making with respect to the instant litigation. The Court further notes that the volume of tape purchases made by Bradburn only amounted to approximately \$12,000 per year. (8/13/03 N.T. at 81.) Thus, by Bradburn's own analysis its individual damages

in this case only total approximately \$11,000. (Pl's Mot. Class Cert. at 20). The attorney's fees that Terry Parkinson's firm will receive from this litigation could easily dwarf this amount. Plaintiff admits that Terry Parkinson has a financial interest in any fees earned by Welsh and Hubble, P.C. (8/13/03 N.T. at 21.)

*11 Accordingly, the Court finds that Bradburn Parent Teacher Store cannot adequately represent the proposed modified class if Terry Parkinson or her law firm, Welsh and Hubble, P.C., continue to represent Bradburn as class counsel. Accordingly, Terry Parkinson and her law firm, Welsh and Hubble, P.C., cannot serve as class counsel and cannot otherwise receive any attorney's fees or other sums which the Court may award in this action.

C. Typicality

In order for Plaintiff to satisfy the typicality requirement, Plaintiff must show that "the claims or defenses of the representative parties are typical of the claims or defenses of the class."  Fed.R.Civ.P. 23(a). "The typicality requirement is intended to preclude certification of those cases where the legal theories of the named plaintiffs potentially conflict with those of the absenteess."
 *Georgine*, 83 F.3d at 631 (citation omitted).

Accordingly, "The inquiry assesses whether the named plaintiffs have incentives that align with those of absent class members so that the absenteess' interests will be fairly represented." *Id.* (citation omitted). The typicality requirement is therefore quite similar to the adequacy of representation requirement, in that "both look to the potential for conflicts in the class." *Id.* On the other hand, the mere existence of factual differences between the claims of class members does not preclude a finding of typicality. Rather, "[f]actual differences will not render a claim atypical if the claim arises from the same event or practice or course of conduct that gives rise to the claims of the class members, and if it is based on the same legal theory."  *Barnes*, 161 F.3d at 141 (quoting 1 *Newberg on Class Actions*, § 3.15, at 3-78); *see also*  *Baby Neal*, 43 F.3d at 58 ("[E]ven relatively pronounced factual differences will generally not preclude a finding of typicality where there is a strong similarity of legal theories.")

In this case, the claims of Plaintiff are typical of the claims of members of the proposed class. Plaintiff asserts

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that all members of the proposed modified class have been injured by the same anticompetitive conduct engaged in by 3M that was the subject of the prior *LePage*'s litigation, and will seek to recover overcharge damages on behalf of these class members. Accordingly, Plaintiff's claim in this case "arises from the same event or practice or course of conduct that gives rise to claims of the class members," and it is based upon the same legal theory.

 *Barnes*, 161 F.3d at 141 (quoting 1 Newberg on Class Actions, § 3.15, at 3-78). Moreover, as discussed, *supra*, the Court finds that the legal theory proposed by Plaintiff will not work to limit or foreclose the recovery of the absent class members. Accordingly, the Court finds that the typicality requirement is satisfied.

D.  *Rule 23(b)(3)* Requirements

Plaintiff asserts that it satisfies the requirements of  *Rule 23(b)(3)*. The prerequisites for certification under  *Rule 23(b)(3)* are as follows:

*12 To qualify for certification under  *Rule 23(b)(3)*, a class must meet two requirements beyond the  *Rule 23(a)* prerequisites: Common questions must "predominate over any questions affecting only individual members"; and class resolution must be "superior to other available methods for the fair and efficient adjudication of the controversy."

 *Amchem Prods.*, 521 U.S. at 615.

In order to succeed in this antitrust action, Plaintiff must prove: 1) a violation of the antitrust laws; 2) antitrust injury resulting from the violation; and 3) the amount of the damages suffered. See  *Stelwagon Mfg. Co. v. Tarmac Roofing Sys., Inc.*, 63 F.3d 1267, 1270-71 (3d Cir.1995). Defendant argues that Plaintiff cannot establish that common questions of fact regarding impact predominate over individual questions.¹⁰ The Third Circuit has held that common issues do not predominate under  *Rule 23(b)(3)* unless impact upon all class members can be established through the use of common proof. See  *Newton v. Merrill Lynch, Pierce, Fenner and Smith, Inc.*, 259 F.3d 154, 189 (3d Cir.2001) ("While obstacles to calculating damages may not preclude class certification, the putative class must first demonstrate

economic loss on a common basis."); *see also In re Linerboard Antitrust Litig.*, 203 F.R.D. at 220 (finding predominance requirement satisfied where "Plaintiffs have shown that they plan to prove common impact by introducing generalized evidence that will not vary among individual class members."). One court has described the requirement as follows:

On a motion for class certification, the issue confronting the court is whether the proof necessary to demonstrate impact as to each class member is particular to that class member, in which case individual questions concerning impact would overwhelm the common questions concerning the existence and scope of [the alleged antitrust violation], or whether the necessary proof of impact would be common to all class members and sufficiently generalized that class treatment of their claims would be feasible.

In re Industrial Diamonds Antitrust Litig., 167 F.R.D. 374, 382 (S.D.N.Y.1996). On the other hand, it is well settled that, if impact can be established by the use of common proof, the fact that individualized determinations of the amount of the damages that each individual class member suffered will be needed does not, in itself, preclude class certification. *See In re*

 *Mercedes Benz Antitrust Litig.*, 213 F.R.D. 180, 190 (D.N.J.2003) (collecting cases); *see also*  *Newton*, 259 F.3d at 189 ("[T]he issue is not the calculation of damages but whether or not class members have any claims at all.") Defendant argues that Plaintiff's expert, Dr. Kamien, has not produced a theory of damages which will allow him to establish the fact of injury for each class member through the use of common proof.

In his expert report, Dr. Kamien opines that,

If 3M's conduct is proven to have restrained competition-by excluding LePage's as a meaningful competitor, and discouraging entry by new competitors or expansion by existing ones-it is economically reasonable to conclude that this has the effect of raising or maintaining prices for all purchasers in the market above what they would have been otherwise. In the

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transparent tape market, the dimensions of competition are price and quality. In that setting, it is standard economic theory that the price will be driven down to the level at which the supplier realizes a reasonable or normal rate of return, taking into account the distinctive quality dimension of his product.

***13** (6/9/03 Kamien Decl. ¶ 9.) Dr. Kamien's theory is fully supported by the *en banc* decision of the Third Circuit in *LePage's II*. In *LePage's II*, the Court wrote:

Once a monopolist achieves its goal by excluding potential competitors, it can then increase the price of its product to the point at which it will maximize its profit. This price is invariably higher than the price determined in a competitive market.

 *LePage's II*, 324 F.3d at 164. Under this line of reasoning, when a monopolist unlawfully maintains its monopoly power in violation of  **Section 2** of the Sherman Act, as is asserted in this case, it is logical, at least as a general rule, to presume that all class members have suffered injury as a result of the conduct, in the form of supra-competitive prices.¹¹

However, Dr. Kamien relies upon far more than a mere theoretical presumption of impact in this case. To the contrary, Dr. Kamien opines that there is a method of economic analysis which can establish the existence of impact upon all potential class members. Dr. Kamien opines that an appropriate measure of damages for the class can be determined in this case using a benchmark, or yardstick, theory. (6/9/03 Kamien Decl. ¶ 10.) A benchmark theory of damages attempts to determine the price that would have been paid for a product in a but-for world absent the defendant's anti-competitive conduct by considering the price actually charged for a different product in a market with similar characteristics unaffected by the anti-competitive conduct, or by considering the

price charged for the product in question during a time period when the defendant did not engage in the anti-competitive conduct in question. (See 6/9/03 Kamien Decl. ¶¶ 10-11). Dr. Kamien opines that two potential benchmarks exist in this case. The first benchmark is the market for transparent tape during the early 1990's, before 3M's anti-competitive conduct commenced. Dr. Kamien opined that, during this period, 3M offered price reductions to a number of customers in response to competition from other suppliers, and that these price reductions can be used as a proxy for the prices that 3M would have charged during the damages period of this case absent its anti-competitive conduct. (6/9/03 Kamien Decl. ¶ 14.) According to Dr. Kamien, data regarding 3M's price reductions during this period should be available from 3M's own records. (6/9/03 Kamien Decl. ¶ 15.) The second benchmark is the market for "wrap and mail" tape during the year 1993. Dr. Kamien opines that during the early 1990's, in response to competition from Manco and other competitors and a resulting loss of market share, Defendant significantly reduced its prices for wrap and mail tape. (6/9/03 Kamien Decl. ¶ 16.) Dr. Kamien bases this proposition on 3M's strategic business plan for the year 1995, which states that a decrease in 3M's market share in the wrap and mail market "was turned in '93, mainly due to a 25% price decrease in mailing tapes and the launch of its mailing supply line." (6/9/03 Kamien Decl. Ex. F at 23.) According to Dr. Kamien, "it should be possible to determine from 3M's cost data in the wrap and mail and transparent tape markets if a similar or greater price decline would have occurred in the transparent tape market." (6/9/03 Kamien Decl. ¶ 17.) Dr. Kamien further opines that "all of the data necessary to determine and apply the benchmarks described above will be available from 3M's own records." (6/9/03 Kamien Decl. ¶ 18.) The two benchmarks proposed by Dr. Kamien are "standard methods for proving damages in an antitrust case." *Nichols v. Smithkline Beecham Corp.*, Civ. A. No. 00-6222, 2003 U.S. Dist. Lexis 2049, at *24 (E.D.Pa. Jan.29, 2003).

***14** Defendant argues that Dr. Kamien's proposed benchmarking theories fail to adequately account for the fact that many of the large-volume retailers were the recipients of bundled rebates and other discounts provided by Defendant, and therefore may have benefitted from the conduct that was challenged in the *LePage's* litigation. Defendant further argues that an individualized determination of the rebates received by each of Defendant's customers would be necessary before the Court could even determine that the class member had

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suffered any injury as a result of Defendant's conduct. Thus, Defendant argues, Dr. Kamien has made no showing that impact can be proven in this case on a common basis.

Dr. Kamien opines in his expert report that "while 3M provides rebates to some customers, 3M's expert witness in the *LePage*'s case testified that '3M's rebate programs are readily convertible into price.'" (6/9/03 Kamien Decl. ¶ 18.) Dr. Kamien further opined that common proof of antitrust injury is available from 3M's own records, which contain data concerning the prices actually charged to 3M's customers as well as 3M's average unit pricing and factory cost. (6/9/03 Kamien Decl. ¶ 18.) For example, Dr. Kamien notes that, according to testimony from 3M's employees, 3M maintains a database which tracks the rebates received by each customer. (See Broderick Dep. at 18; *see also* Rubinfeld Dep. at 177-78). Based upon his proposed benchmark theory and the availability of this evidence, Dr. Kamien testified at the hearing that "the magnitude of the damage [suffered by each class member] can be calculated in a common way." (8/13/03 N.T. at 92.)

Defendant argues that Dr. Kamien has merely assumed the existence of impact in this case, without any empirical or theoretical basis for this assumption. Dr. Kamien did admit at the hearing that, for purposes of his research, he assumed the existence of common impact among class members. However, Dr. Kamien explained that this assumption was based upon the allegations made in Plaintiff's Complaint, which he assumed to be true for purposes of his research.¹² (11/4/03 N.T. at 108-11.) Dr. Kamien's admission is in no way fatal to class certification, because Plaintiff is not required at this stage of the litigation to establish, as fact, that each class member has suffered economic injury.¹³ See *Lumco Indus., Inc. v. Jeld-Wen, Inc.*, 171 F.R.D. 168, 173-74 (E.D.Pa.1997) ("At this stage of litigation, however, the Court need not concern itself with whether Plaintiffs can prove their allegations regarding common impact; the Court need only assure itself that Plaintiffs' attempt to prove their allegations will predominantly involve common issues of fact and law."); *see also Nichols*, 2003 U.S. Dist. Lexis 2049, at *20 ("In order to show impact is susceptible to class-wide proof, Plaintiffs are not required to show that the fact of injury actually exists for each class member. If Plaintiffs are able to establish the existence of generalized evidence which will prove or disprove this injury element on a simultaneous class-wide basis, then there is no need to examine each class members' individual circumstance.") (internal quotation

marks omitted.) Rather, it is Plaintiff's burden to "make a threshold showing that the element of impact will predominantly involve generalized issues of proof, rather than questions which are particular to each member of the proposed class." *Lumco*, 171 F.R.D. at 174. Plaintiff maintains that it has met this burden by presenting, through Dr. Kamien, a theory of damages which will prove or disprove the existence of impact for all members of the class by the use of common benchmarking formulas and generalized proof.

*15 Defendant argues, however, that Dr. Kamien's opinion lacks foundation, because he has not made an adequate demonstration that he has studied the market for transparent tape, or the market for wrap and mail tape, in the United States. Furthermore, Defendant argues that, given the complexities inherent in these markets, the methodologies that Dr. Kamien proposes for proving classwide impact cannot feasibly be applied to the facts of this case.

Defendant relies upon *In re Linerboard Antitrust Litig.*, in which the Third Circuit highlighted the need for expert witnesses to support their expert opinions with supporting data and collaborating opinions. The *Linerboard* court credited the testimony of the plaintiff's expert witnesses, who opined that an alleged conspiracy among producers of linerboard to reduce their inventories would have had a common, class-wide impact. The court did so in large part because the experts' opinions "were supported by charts, studies and articles from leading trade publications." *Linerboard*, 305 F.3d at 153. Specifically, the expert witnesses had conducted "extensive empirical investigation[s]" into the market for linerboard and corrugated boxes. *Id.* Thus, the expert's conclusions were not generalized theories, but were instead based upon a specific analysis of the actual conditions present in the relevant market. *Linerboard*, therefore, teaches that at least some analysis of the relevant market and other facts unique to the particular case is required before an expert can opine that all class members have suffered antitrust injury. Compare  *Weisfeld v. Sun Chemical Corp.*, 210 F.R.D. 136, 143 (D.N.J.2002) (finding that Plaintiff had failed to satisfy the predominance requirement where Plaintiff offered "no ... support for his claim of classwide impact, only the naked conclusions of his expert.") with

 *Daniel v. American Bd. of Emergency Medicine*, 269 F.Supp.2d 159, 201 (W.D.N.Y.2003) (predominance requirement satisfied where expert's "opinion is based upon a substantial body of independently created data tending reasonably to confirm his preliminary conclusions

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as to the classwide impact of Defendants' [alleged unlawful conduct] upon the compensation of the proposed class.")

The Court finds that Dr. Kamien has sufficiently augmented his conclusion that classwide impact can be established through the use of common proof with supporting documentation and economic theory. The Court further finds that this supporting documentation demonstrates that Dr. Kamien has conducted at least a preliminary study of the market for transparent tape and the feasibility of applying his economic theory to this market. For example, in support of his assertion that the market for "wrap and mail" tape represents a valid competitive benchmark for this case which may be used to calculate damages on a common basis for the entire class, Dr. Kamien utilized Defendant's own internal strategic business plan, which states that 3M regained market share lost in the early 1990's from emerging competition by lowering the price of its wrap and mail products substantially. (6/9/03 Kamien Decl. ¶ 16 & Ex. F.) Dr. Kamien's analysis of the market for transparent tape prior to 3M's anti-competitive conduct similarly cites to both deposition testimony of 3M employees and *LePage*'s trial testimony to support Dr. Kamien's assertion that the discounts offered by 3M during this period can be used as a proxy for determining the prices that 3M would have charged for its tape in the absence of its anti-competitive conduct. The Court therefore finds that Dr. Kamien has supported his expert opinion with "sufficient evidence and a plausible theory to convince the Court that class-wide impact ... may be proven by evidence common to all class members."  *Mercedes-Benz*, 213 F.R.D. at 190.

*16 Defendant also points out several characteristics of the markets for transparent tape and wrap and mail tape that it alleges Dr. Kamien failed to consider, and which demonstrate that Dr. Kamien's proposed methods for establishing impact through the use of common proof will not work in this case. For example, Defendant notes that Dr. Kamien was unaware that Defendant actually utilized bundled rebates in the wrap and mail market, making it an inadequate competitive benchmark. (Def's Opp. Class Cert at 51). Plaintiff notes, however, that bundled rebates were used in the wrap and mail market for the first time in 1993 as part of a pilot program. Plaintiff further notes that the bundled rebate test program only applied to thirteen purchasers during the year 1993. Dr. Kamien testified that, because the bundled rebate programs took a number of years to achieve an effect upon pricing in the markets

in which they were used, the market for wrap and mail tape during the year 1993 could still be used as a benchmark notwithstanding the existence of the bundled rebate program. (Kamien Dep. at 100.) Defendant also argues that, according to its research, and contrary to Dr. Kamien's assertions, there was no general 25% decrease in the price of wrap and mail tape in the year 1993. Rather, according to Dr. Rubinfeld, 3M decreased the price of only two of the products in its wrap and mail line in January 1993. (5/17/04 Rubinfeld Decl. ¶ 18.) According to Dr. Rubinfeld, the prices of other wrap and mail products were left unchanged in 1993. (*Id.*) Furthermore, according to Dr. Rubinfeld, in January 1995, the prices of these two tape products were further reduced, while the prices of other wrap and mail tapes were increased slightly. (*Id.*) According to 3M, this evidence demonstrates that the price trends in the wrap and mail market in response to competition were not consistent or uniform. Accordingly, 3M argues, because there was no common impact from competition on price in the wrap and mail market, this market cannot provide an adequate competitive benchmark. Dr. Kamien responds that he does not believe that this new information, in itself, indicates that the wrap and mail market cannot serve as an appropriate benchmark in this case. Dr. Kamien notes specifically that he does not yet have access to the gross margins on wrap and mail products. (6/4/04 N.T. at 19.)¹⁴ It is the gross margins for products in the wrap and mail market, Dr. Kamien argues, that will allow him to determine 3M's response to the entry of competitors in a competitive market, not movements in the price charged to the end user. (*Id.*) This is because, without the gross margin data, it is not possible to determine if the price fluctuations on certain wrap and mail products were caused by, for example, fluctuations in the cost of production, as opposed to 3M's decision to selectively reduce prices in response to competition. (*Id.*) Moreover, Dr. Kamien points out that he does not yet know the market share of the two wrap and mail products for which 3M reduced prices 25%. (6/4/04 N.T. at 18). Dr. Kamien notes that, if these two products were the "big sellers" in this market, it would make sense for 3M to lower the price of these two products, as opposed to the price on products which sold in smaller volumes, in order to regain market share. (*Id.*)

*17 The Court finds that Dr. Kamien's testimony provides a sufficient rebuttal to Defendant's argument that factors unique to the transparent tape market would render Dr. Kamien's proposed benchmarking analysis inadequate in this case. Accordingly, the dispute between Plaintiff and Defendant as to whether Dr. Kamien's

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benchmarking analysis will work in this case is not appropriately considered at this time. See *In re Visa Check/Master Money Antitrust Litig.*, 280 F.3d at 135 (noting that, at class certification stage of litigation, a court “may not weigh conflicting expert evidence or engage in statistical dueling of experts.”) (citation omitted). It will be for a jury deciding the merits of this litigation, after the parties have had the full benefit of discovery, to evaluate the conflicting testimony of Plaintiff’s and Defendant’s experts and determine the weight that Dr. Kamien’s expert opinion deserves. See *In re Domestic Air Transp. Litig.*, 137 F.R.D. 677, 692 (N.D.Ga.1991) (“It is not the function of the Court at [the class certification stage] to determine whether [the expert witness] is correct. The weight to be given his testimony and its effect is for the fact finder in assessing the merits of plaintiffs’ claims at a later date.”)

Defendant also attacks Dr. Kamien’s proposed use of the market for transparent tape before Defendant’s conduct began as a benchmark because, according to Defendant, Plaintiff has made no showing that the data needed to do this benchmarking analysis is available. (Def’s Opp. Class Cert. at 49-50.) However, as the parties are well aware, Defendant objected to the disclosure of pricing and competitive information for 3M’s invisible and transparent tape for the period from 1989 through 1991 during the class certification phase of this action, and the Court thereafter denied Plaintiff’s Motion seeking this information before the commencement of merits discovery. (See 3/31/03 Order, Docket # 32.) Furthermore, Defendant has not alleged that this data, which ostensibly would allow Dr. Kamien to conduct his analysis, is not available, nor has it provided a credible reason to explain why such data would not be available. Defendant further attacks Dr. Kamien’s benchmarking methodology for failing to take into account the complexities of the market for transparent tape. Specifically, Defendant relies upon the fact that there are more than 1,000 different tape products in the market definition of transparent tape, and that the prices for each product vary greatly depending upon the customer and the time period. However, while it may be true that Defendant produces nearly 2,000 different product stock keeping units (“SKU’s”) that would be included in the transparent tape market definition, Mr. Kaplan, one of Defendant’s expert witnesses, testified that only 100 of these SKU’s comprise approximately 80% of 3M’s sales. (11/4/03 N.T. at 75.) Dr. Kamien opines that one can approximate the pricing behavior of the remaining 1,900 SKU’s by examining the pricing behavior of the top 100

SKU’s, because one would expect that the prices of the remaining SKU’s would have behaved in a similar manner. (8/13/03 N.T. at 161-62.) Furthermore, Dr. Rubinfeld has admitted that Defendant maintains databases which track the prices that Defendant charges each individual customer for each product it sells, and that these databases contain promotional allowances and rebates, as well as other discounts offered to each customer. (Rubinfeld Dep. at 177-78). Furthermore, the existence of market complexity does not in itself necessarily mandate the use of individualized proof of impact. Rather, courts have granted class certification in cases where many of the proposed class members payed individually negotiated prices. For example, in *Industrial Diamonds*, the court certified a class of plaintiffs who paid individually negotiated prices for industrial grade diamonds for which a list price was set. 167 F.R.D. at 383-84. The *Industrial Diamonds* court rejected the defendant’s argument that the individually negotiated prices made an individualized determination of damages necessary, noting that, if plaintiffs could prove at trial that the “[the] list prices were the basis for individual price negotiations between defendants and their customers, a jury could reasonably conclude that the purchasers of list-price products were impacted by the alleged [price fixing] conspiracy.” *Id.* at 384; see also *In re Flat Glass Antitrust Litig.*, 191 F.R.D. 472, 486 (W.D.Pa.1999) (“even though some plaintiffs negotiated prices, if plaintiffs can establish that the base price from which these negotiations occurred was inflated, this would establish at least the fact of damage, even if the extent of the damage [suffered] by each plaintiff varied.”) (citations omitted); *Mercedes Benz*, 180 F.R.D. at 189 (crediting expert’s conclusion that common proof of impact would be possible even where putative plaintiffs each negotiated individual prices for their automobiles); *Rosack v. Volvo of America Corp.*, 131 Cal.App.3d 741, 182 Cal.Rptr. 800, 811 (Cal.App.1982) (“The good negotiator in the fixed market would presumably have gotten an even better deal in the competitive market.”) In this case, Plaintiff has asserted that the discounts that individual customers received were discounts off of a monopoly price. (See Compl. ¶ 27.)

*18 Accordingly, the Court finds that Plaintiff has adduced sufficient evidence and a plausible theory to support its proposition that common evidence is available which will establish the existence of impact for each potential class member. The Court therefore finds that common questions predominate over individual questions with respect to Defendant’s violation of the antitrust laws

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and with respect to impact.

The Court further finds that a class action is the superior method for the fair and efficient adjudication of this dispute.  Rule 23(b)(3) provides a list of four factors which are relevant in determining this issue. The factors are:

(A) The interest of members of the class in individually controlling the prosecution or defense of separate actions; (B) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class; (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; (D) the difficulties likely to be encountered in the management of a class action.

 Fed R. Civ. P. 23(b)(3). As Plaintiff points out, there are a substantial number of potential class members whose recovery in this case would be dwarfed by litigation costs associated with bringing this suit. Accordingly, bringing this suit as a class action "provides an efficient alternative to individual claims, ... because individual Class members are unlikely to bring individual actions given the likelihood that their litigation expenses would exceed any potential recovery." *Orloff v. Syndicated Office Sys., Inc.*, 00-CV 5355, 2004 WL 870691, at *5 (E.D.Pa. Apr.22, 2004) (citation omitted). To be sure, the modified class may include members who have purchased a sufficiently large quantity of tape from 3M to justify the commencement of an individual suit. However, the class also contains many members whose potential damage awards would be dwarfed by their potential litigation expenses. Indeed, as noted, *supra*, Plaintiff's potential damages in this case are estimated to be only approximately \$11,000. Furthermore, many of the largest purchasers of 3M tape were also purchasers of private label tape, and would, therefore, not be included in the modified class. (See Pl's Renewed Mot. Class Cert. Ex. B, "Kaplan Dep.", Ex. 10.) 3M argues that class certification is not appropriate in light of the fact that two

purchasers of 3M tape have already publicly stated their opposition to this lawsuit. However, Plaintiff contends that neither of these purchasers would be included in the modified class, and Defendant has pointed to nothing which refutes Plaintiff's contention. (See Pl's 5/7/04 Reply Mem. at 21.) Defendant also argues that the fact that no member of the class has sought to file an individual action in this case weighs against class certification. However, as Plaintiff points out, this is as likely the result of the fact that potential class members cannot afford the costs of an individual suit as it is the result of class members' disinterest in the underlying lawsuit. Finally, 3M argues that concerns over the adequacy of Bradburn's representation of the proposed class militate against a finding that a class action is the superior method of proceeding with this litigation. However, as discussed, *supra*, the Court has already found that Bradburn is an adequate representative of the class. Accordingly, it would not be appropriate to revisit this issue in considering whether the superiority requirement is met.

V. CONCLUSION

*19 For the foregoing reasons, Plaintiff's Motion for Class Certification will be granted, subject to the condition that Terry Parkinson and her law firm, Welsh and Hubble, P.C., will not serve as class counsel in this action and will not otherwise be entitled to any attorney's fees or other sums which the Court may award in this action.

An appropriate order follows.

ORDER

AND NOW, this ____ day of August, 2004, upon consideration of Plaintiff's Motion for Certification of Modified Class (Doc. # 140), all related submissions, and the hearings held on June 4, 2004 and June 9, 2004, IT IS HEREBY ORDERED that Plaintiff's Motion is GRANTED. The following class of Plaintiffs shall be certified:

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All persons who directly purchased invisible or transparent tape from 3M Company between October 2, 1998 and the present, who have not purchased, for resale under the class member's own label, any "private label" invisible or transparent tape from 3M Company or any of 3M Company's competitors at any time from October 2, 1988 to the present.

IT IS FURTHER ORDERED that the class claims and issues shall be those set forth in the Complaint, and that the following shall serve as class counsel pursuant to

 Fed.R.Civ.P. 23(g):

R. Steven Berry, Berry and

Footnotes

Leftwich J. Daniel Leftwich, Berry and Leftwich Gregory Baruch, Berry and Leftwich Charles M. Jones, Jones, Osteen, Jones and Arnold

The law firm of Welsh & Hubble, P.C. shall not serve as class counsel.

IT IS FURTHER ORDERED that the parties shall confer as to a plan of Class notice and shall submit such plan within twenty (20) days from the date of this Order.

All Citations

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- ¹ As described at length in the LePage's litigation, Defendant's bundled rebate programs provided purchasers with significant discounts on Defendant's products. However, the availability and size of the rebates were dependant upon purchasers buying products from Defendant from multiple product lines. See  *LePage's II*, 324 F.3d at 154-55.
- ² Private label tape was defined by the Third Circuit in *Lepage's II* as "tape sold under the retailer's name rather than under the name of the manufacturer."  *LePage's II*, 324 F.3d at 144.
- ³ At a subsequent hearing, Dr. Rubinfeld testified that "I think it's likely that this [the market segmentation theory] would be a successful approach," for substantial purchasers of second tier tapes. (6/9/04 N.T. at 60.) However, Dr. Rubinfeld did not testify that the damages for substantial purchasers of second tier tapes would likely be higher under a market segmentation theory than they would under a one market theory.
- ⁴ The Court agrees with Plaintiff's assertion that the potential conflict in the instant case is quite similar to the conflict presented to the court in  *In re Visa Check/Master Money Antitrust Litig.*, 280 F.3d 124 (2d Cir.2001). In that case, the United States Court of Appeals for the Second Circuit ("Second Circuit") considered the certification of a proposed class of merchants who accepted Visa and Mastercard credit and debit cards as a form of payment. Plaintiff argued that Defendant had created an illegal tying arrangement by forcing retailers who accepted Visa and Mastercard credit cards to also accept Visa and Mastercard debit cards for payment. The class included retailers who primarily conducted credit card transactions, as well as retailers who primarily conducted debit card transactions. Defendant argued that the potential for conflict between class members was high, as those class members who mainly conducted credit card transactions would have the incentive to argue that the cost of credit card transactions would not have risen in the absence of the tie, in order to maximize their recovery. By contrast, retailers who mainly conducted debit card transactions would have far less interest in pursuing such a strategy, and

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would instead wish to concentrate their efforts in demonstrating that the price of debit card transactions would have fallen in the absence of the tie. The Second Circuit, with one judge dissenting, rejected this argument, reasoning that, while the price of credit card transactions absent the tie would be less relevant to the recovery of retailers who predominantly conducted debit card transactions, *all* potential class members would benefit from a showing that the prices for credit card transactions would have stayed the same, or risen negligibly, in the absence of the tie.  *Id.* at 144-45. The court wrote

It may be less vital for merchants with predominantly debit card sales to prove the credit cards would be no more expensive without the tie.... [However], it would seem to maximize the potential recovery of all three groups to argue, as they do here, that credit card prices would not increase without the tie.

Id. at 144.

- ⁵ The Court made this point in its prior Memorandum denying Plaintiff's original motion for class certification. In that Memorandum, the Court noted that "the Court cannot find as fact on a motion for class certification that either one of [two competing] theories is correct."  *Bradburn Parent/Teacher Store v. 3M*, No. 02-7676, 2004 WL 414047, at *7 (E.D.Pa. Mar.1, 2004).

Of course, a plaintiff must still present a credible theory of damages which will demonstrate impact upon all class members through the use of common proof. See  *Newton v. Merrill Lynch, Pierce, Fenner and Smith, Inc.*, 259 F.3d 154, 189 (3d Cir.2001) ("While obstacles to calculating damages may not preclude class certification, the putative class must first demonstrate economic loss on a common basis.") This issue is discussed *infra* in connection with the Court's analysis of whether Plaintiff has satisfied the requirements of  Rule 23(b)(3).

- ⁶ In denying Plaintiff's previous motion for class certification, the Court held that the opt out procedure described in  Rule 23(c)(2) failed to cure the conflicts inherent in the proposed class, because, the Court noted, the conflict between class members would exist "from the moment that the class were certified." This was due to the fact that there were two competing theories relevant to proving damages in the case, and Plaintiff's pursuit of one theory in order to maximize its damages would likely work to minimize the recovery available to other class members. By contrast, in this case, as discussed, *supra*, Plaintiff's one market theory of damages runs a serious risk of minimizing the recovery of other members of the modified class only if the theory is rejected by a fact-finder on the merits.

In its prior opinion, the Court also found the opt out procedure in  Rule 23(c)(2) inappropriate because many of the class members who traded in private label tape were among the largest members of the proposed class. The Court noted that, despite their size and apparent ability to pursue an individual action for damages, none of the proposed class members had shown any interest in doing so. By contrast, in this case, there has been no showing that a substantial number of members of the modified class who purchased mainly or solely second tier 3M transparent tape did a sufficiently large business in transparent tape to justify the costs of an individual suit.

- ⁷ Based upon *Koppel and Jane B.*, as well as other cases arising out of the Southern District of New York, Plaintiff argues that the Court should announce a bright line rule that prior bad acts of a proposed class representative are only relevant to class certification if either 1) the questionable conduct of which the proposed class representative is accused is related to the proposed representation, or, 2) if there has been a prior judicial finding of misconduct. Although these two factors are highly relevant to a court's determination of the adequacy of a class representative, the Court declines to hold that these factors, or any other factors, must be established before a class representative's integrity is sufficiently called into question to defeat class certification. For example, requiring a prior judicial finding of misconduct might be inappropriate in a case where a defendant admits to engaging in the conduct in question in the current proceedings before the court.

- ⁸ For example, Ms. Parkinson testified during the class certification hearing that her vacation trip to Maine was charged to the company card because she had visited stationary stores in the New England area during the trip to

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determine the manner in which they were run. (8/13/03 N.T. at 63.)

⁹ On the other hand, a judge in this district certified a class in spite of the fact that one of the named class representatives was a partner in the law firm that represented the class (the other named representatives were siblings of the law partner). See *Umbriac v. American Snacks, Inc.*, 388 F.Supp. 265 (E.D.Pa.1975). The court in *Umbriac* reasoned that, although the potential for attorney's fees might cloud the judgment of the class representatives, because all compromises and settlements would require court approval (see *Fed R. Civ. P. 23(e)*), the interests of the other class members would be protected. This decision has not been followed by other courts. See *Flamm v. Eberstad*, 72 F.R.D. 187, 189 (E.D.Ill.1976) (refusing to follow *Umbriac*, and noting that in its research it had found only one other case which had allowed a class representative to serve as class counsel.) Moreover, while the Court recognizes its power to disapprove settlement agreements which are not in the best interest of the class as a whole, the Court considers this power to be an additional protection of the interests of the class members, and not a substitute for the requirement that a class representative's interests align with the interests of other members of the class and not with the interests of its attorneys.

¹⁰ Defendant does not appear to dispute Plaintiff's claim that common questions regarding Defendant's alleged violation of the antitrust laws predominate over individual questions. Furthermore, it appears that under Plaintiff's theory of the case this element will be established through common proof, and specifically through the proposed use of collateral estoppel and the findings from the *LePage*'s litigation. (See Compl. ¶ 17.) The Court therefore finds that common questions predominate over individual questions with respect to Defendant's alleged violation of the antitrust laws.

¹¹ The Court does not read *LePage's II* as precluding a defendant in a case brought under *Section 2* of the Sherman Act from challenging the existence of common proof with respect to impact by presenting evidence tending to show that, under the particular circumstances of the case, impact cannot be demonstrated by common proof. See *Industrial Diamonds*, 167 F.R.D. at 382 (noting that, while, as a general rule, an illegal price fixing conspiracy presumptively impacts all purchasers of the product in the affected market, a defendant in such a case is always free to argue that factors peculiar to the specific industry and market involved rebut any presumption that all class members have been impacted and preclude the use of common proof to establish such impact).

¹² The Complaint in this action alleges that "3M's unlawful maintenance of its tape monopoly has suppressed competition and has maintained tape prices paid by direct purchasers to 3M well above competitive levels after any 3M rebates (if any) attributable to tape purchases." (Compl. ¶ 27.)

¹³ Defendant relies heavily upon *Newton*, 259 F.3d 154, a securities class action in which Plaintiff alleged that broker-dealers breached their duty of best execution when trading their customers' securities on the NASDAQ exchange. In *Newton*, the Third Circuit held that the predominance requirement was not satisfied where an inquiry into the circumstances of hundreds of millions of individual stock trades would be required to determine whether or not each member of the proposed class failed to receive the best available price and was therefore injured by the alleged improper conduct. See *id.* at 187-88. The *Newton* court wrote that "because it is clear that at least some of the plaintiffs have not suffered economic injury, individual questions remain that would have to be adjudicated separately." *Id.* at 190. The Court finds the facts of the instant case easily distinguishable from those in *Newton*. First, unlike in *Newton*, it is not at all clear in this case that there are class members who have not suffered economic injury. To the contrary, the trial court record in *LePage*'s lends support to Plaintiff's allegation that all members of the proposed class were harmed by Defendant's anti-competitive conduct. Indeed, the Third Circuit noted in its *en banc* opinion that, "*LePage*'s expert testified that the price of Scotch-brand tape increased since 1994, after 3M instituted its rebate program." *LePage's II*, 324 F.3d at 164. Second, and more importantly, in this

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case Plaintiff has pointed to the existence of common proof, specifically Defendant's internal databases, which will affirmatively establish the impact of Defendant's conduct upon each of the members of the proposed class. Thus, this Court will not likely be faced with anything approaching the "herculean" task of examining hundreds of millions of individual transactions that would have been required of the Court in *Newton*.

- ¹⁴ In a prior order, the Court denied Plaintiff's request seeking "discovery regarding pricing, profits and competitive information for Defendant's office products other than invisible and transparent tape since 1992." (See 3/31/03 Order, Docket # 32.)

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Exhibit 2

Case Management Order No. 1, *In re Nat'l Prescription Opiate Litig.*,
No. 1:17-md-02804 [Dkt. No. 232] (N.D. Ohio Apr. 11, 2018)

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**
APPLIES TO ALL CASES

Case No. 1:17-CV-2804
Hon. Dan A. Polster

CASE MANAGEMENT ORDER ONE

The parties in this case have been pursuing, and are continuing to pursue, settlement discussions, and they have made good progress. The parties have indicated, however, they believe settlement will be made more likely if, in addition to the “settlement track” they are currently pursuing, the Court also creates a “litigation track.” Accordingly, the Court hereby enters this Case Management Plan, which directs the parties to engage in motion practice, discovery, and trial preparation for certain cases in this MDL.

1. APPLICABILITY AND SCOPE OF ORDER

a. **Scope.** This CMO is intended to conserve judicial resources, reduce duplicative service, avoid duplicative discovery, serve the convenience of the parties and witnesses, and promote the just and efficient conduct of this litigation. *See Fed. R. Civ. P. 1.* This Order and, unless otherwise specified, any subsequent pretrial or case management orders issued in this MDL, shall govern the practice and procedure in: (1) those actions transferred to this Court by the Judicial Panel on Multidistrict Litigation (“JPML”) pursuant to its order entered on December 5, 2017, (2) any tag-along actions transferred to this Court by the JPML pursuant to Rules 7.1 and 7.2 of the Rules of Procedure of the Panel, after the filing of the final transfer order by the Clerk of the Court, and (3) all related actions originally filed in this Court or transferred or removed to this Court and assigned thereto as part of *In re: National Prescription Opiate*

Litigation, MDL No. 2804 (“MDL 2804”). These cases will be referred to as the “MDL proceedings.”

The provisions of this Order, and any subsequent pretrial order or case management order issued in the MDL proceedings, shall supersede any inconsistent provisions of the Local Rules for the United States District Court, Northern District of Ohio (“Local Rules”). The coordination of MDL Proceedings, including certain of these cases that have been or may be directly filed into this MDL, does not constitute a waiver of any party’s rights under *Lexecon v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998). This CMO shall not be construed to affect the governing law or choice-of-law rules in any case subject to the CMO.

b. **Application to All Parties and Counsel.** This Order and all subsequent pretrial or case management orders shall be binding on all parties and their counsel in all cases currently pending, or subsequently transferred to, removed to, or pending in the MDL proceedings, and shall govern each case in the MDL proceedings unless the order explicitly states that it relates only to specific cases.

c. **Amendment and Exceptions.** This Order may be amended by the Court on its own motion, and any party may apply at any time to this Court for a modification or exception to this Order. The Court expects it will issue subsequent case management orders addressing the cases mentioned in this CMO and other MDL proceedings.

2. **MOTIONS TO DISMISS**

a. The parties and Court agree that it will be efficient and informative to proceed with briefing on threshold legal issues on common claims. Accordingly, the Court sets out below a process for choosing certain cases to brief these threshold legal issues, where these cases: (1) are filed in a representative variety of jurisdictions, (2) by a representative variety of

Plaintiffs, (3) against a representative variety of Defendants, and (4) which raise a representative variety of issues.

b. **Cases filed by local governmental entities in Ohio and Illinois.** No later than Wednesday, April 25, 2018, and subject to paragraph 2.j, Plaintiffs in the following cases shall amend their Complaints or provide notice that the Complaint will not be amended, and Defendants may file motions to dismiss in any or all of these cases within **28 days thereafter**: (1) *The County of Summit, Ohio. v. Purdue Pharma L.P.*, Case No. 18-OP-45090 (N.D. Ohio); and (2) *The City of Chicago, Illinois v. Purdue Pharma L.P.*, Case No. 17-OP-45169 (N.D. Ohio).

c. **Cases filed by local governmental entities in West Virginia, Michigan, and Florida.** No later than Wednesday, April 25, 2018, and subject to paragraph 2.j, Plaintiffs in the following cases shall amend their Complaints or provide notice that the Complaint will not be amended, and Defendants may file motions to dismiss in any or all of these cases within **42 days thereafter**: (1) *Cabell County Commission, West Virginia v. AmerisourceBergen Drug Corp.*, Case No. 17-OP-45053 (N.D. Ohio); (2) *County of Monroe, Michigan v. Purdue Pharma L.P.*, Case No. 18-OP-4515 (N.D. Ohio); and (3) *Broward County, Florida v. Purdue Pharma L.P.*, Case No. 18-OP-45332 (N.D. Ohio).

d. **Cases filed by Sovereigns – Alabama and Indian Tribes.** No later than Wednesday, May 9, 2018, and subject to paragraph 2.j, Plaintiff in the following case shall amend the Complaint or provide notice that the Complaint will not be amended, and Defendants may file motions to dismiss within **42 days thereafter**: *The State of Alabama v. Purdue Pharma L.P.*, Case No. 18-OP-45236 (N.D. Ohio). In addition, the Court will issue a supplemental case management order addressing the Indian Tribes cases.

e. **Cases filed by Hospitals and Third-Party Payors. No later than Friday, May 11, 2018,** the Hospital Representative of the Plaintiffs' Executive Committee ("PEC") shall identify for the parties and the Court a single MDL case filed by a hospital, the claims of which are governed by the law of one of the States listed in paragraphs 2.b and 2.c. Furthermore, **no later than Friday, May 11, 2018**, Defendants shall notify the parties and the Court that they have identified a single MDL case filed by a third-party payor, the claims of which are governed by the law of one of the States listed in paragraphs 2.b and 2.c. The Court will issue a subsequent case management order setting deadlines in these cases.

f. Plaintiffs may respond to the motions in each of the above actions within **28 days** after the motions are filed, and Defendants may file replies within **21 days** thereafter. State Attorneys General may file amicus briefs in response to any motions to dismiss filed in *State of Alabama v. Purdue Pharma L.P.*

g. The parties shall endeavor to coordinate and consolidate briefing on all of the motions to dismiss and avoid duplicative briefing by incorporating similar arguments by reference. For example: (1) manufacturer Defendants shall endeavor to file a single motion to dismiss in each case, addressing issues common to all manufacturers; (2) distributor Defendants shall endeavor to file a single motion to dismiss in each case, addressing issues common to all distributors; (3) manufacturer and distributor Defendants shall endeavor to present common issues together; (4) the parties shall not repeat arguments in subsequent cases or briefs; (5) Defendants shall raise only those issues they believe are most critical and most relevant to the settlement process; and so on.

h. The Court will strictly enforce provisions regarding length of memoranda filed in support of motions; and the Court will apply limitations applicable to complex cases. *See*

Local Rule 7.1. Motions for relief from the length restrictions must show good cause for such relief and must be made sufficiently in advance to permit the Court to rule and the Clerk's Office to issue the ruling by regular mail. Motions for relief from length restrictions which are filed contemporaneously with the memorandum exceeding the page limits will be denied. In no event shall the request to exceed page limitations extend the time for filing of the underlying memorandum.

i. Chambers will not accept courtesy copies of motions or briefs unless expressly requested by the Court. Exception: motions or briefs filed within two (2) business days of a conference/hearing/trial shall be emailed to the Court as well as opposing counsel on the same day it is filed. The Court's email address for these filings is Polster_Chambers@ohnd.uscourts.gov. Also, counsel shall provide to Special Master Cohen: (1) three-hole-punched, two-side-printed, written copies of all papers related to the motions to dismiss; and (2) thumb-drives containing as-filed PDFs of all papers related to the motions to dismiss, and also PDFs of all cases cited.

j. Defendants do not waive and shall be deemed to have preserved any defenses not addressed in the initial motions filed pursuant to the foregoing provisions, including but not limited to insufficient service of process and lack of personal jurisdiction. Further, nothing in this Order is intended to waive any Defendant's right to file an individual motion to dismiss in any or all of the above-listed cases in the future on any grounds, including lack of personal jurisdiction.

k. Nothing in this Order is intended to waive any Plaintiff's right to move to file further amended pleadings in the above-listed cases if deemed appropriate. Defendants reserve all rights related to any such motion or filings.

3. **CASE TRACKS**

a. **Track One.** The following three cases are included in Track One: (1) *The County of Summit, Ohio. v. Purdue Pharma L.P.*, Case No. 18-OP-45090 (N.D. Ohio); (2) *The County of Cuyahoga v. Purdue Pharma L.P.*, Case No. 17-OP-45004 (N.D. Ohio); and (3) *City of Cleveland v. AmerisourceBergen Drug Corp.*, Case No. 18-OP-45132 (N.D. Ohio).

b. **Amendments to Track One Complaints. No later than Wednesday, April 25, 2018,** Plaintiffs in Track One Cases shall amend their Complaints or provide notice that the Complaint will not be amended at this time.

c. **Written Discovery in Track One.** Subject to the parameters in paragraph 9 below, written discovery in Track One Cases shall commence upon entry of this Order.

d. **Insurance Information in Track One Cases.** Pursuant to Fed. R. Civ. P. 26(a)(1)(A)(iv), the parties shall produce any insurance agreements under which an insurance business may be liable to satisfy all or part of a possible judgment in the Track One Cases, or to indemnify or reimburse for payments made to satisfy any judgment. This includes agreements insuring against general liability, product liability, druggist liability, directors and officers liability, and any other applicable agreements. The parties shall also produce charts that depict the insurance coverage that is or may be applicable to the claims in the Track One Cases. The insurance agreements and coverage charts shall be produced within **30 days of the issuance of the protective order** referred to in paragraph 9.d. The protective order shall include a provision that permits the parties' insurance companies to have access to, and communicate concerning, the materials produced in the Track One Cases.

e. **Depositions in Track One Cases.** Depositions of parties will proceed in the Track One Cases as set forth below.

i. The parties will meet and confer and submit a proposal, **no later than Monday, May 21, 2018**, regarding numerical limits on fact witness depositions.

ii. Beginning on **June 4, 2018**, the parties may begin noticing fact witness depositions, which shall be completed by **August 31, 2018**.

f. **Close of Fact Discovery in Track One Cases.** Fact discovery in the Track One Cases shall be completed by **August 31, 2018**.

g. **Expert Discovery in Track One Cases.**

i. By **September 7, 2018**, Plaintiffs shall serve expert reports in the Track One Cases and, for each expert, provide two proposed deposition dates between **September 17 and October 5, 2018**.

ii. By **October 12, 2018**, Defendants shall serve expert reports in the Track One Cases and, for each expert, provide two proposed deposition dates between **October 22 and November 9, 2018**.

h. **Schedule for Daubert and Dispositive Motions in Track One Cases.**

November 16, 2018 Deadline for *Daubert* and dispositive motions in Track One trial cases.

December 14, 2018 Deadline for responses to *Daubert* and dispositive motions.

January 7, 2019 Deadline for replies in support of *Daubert* and dispositive motions.

Week of January 14, 2019 Hearing on *Daubert* and dispositive motions, or as otherwise set by the Court, if necessary.

i. **Initial Trial Setting.** The Court's current intention is to consolidate all three Track One Cases for trial, and to try all then-surviving claims against all then-surviving

Defendants. The Court intends to begin the trial at **9:00 a.m. Eastern Time on Monday, March 18, 2019**, to last for a period of three weeks. The parties shall meet and confer and submit to the Court, **no later than Friday, January 25, 2019**, joint or competing proposals addressing issues relating to the structure of the first trial and deadlines for other pretrial submissions and additional activities through trial. The Court may accept or modify completely the parties' proposals.

j. **Additional Case Tracks.** The parties and the Special Masters shall confer by **August 17, 2018**, to adopt a process and schedule for additional case tracks, which shall involve cases from the state and tribal jurisdictions identified in paragraph 2. These additional cases need not necessarily be the cases listed in paragraph 2. The parties and the Special Masters shall confer regularly as the Track One cases progress, to determine whether any modifications to this CMO are necessary, including whether any other cases should be set for discovery.

4. ELECTRONIC FILING PROCEDURES

The parties are expected to follow the Northern District of Ohio's policies and procedures on Electronic Case Filing. All counsel of record are hereby directed to take steps as necessary to be registered as electronic filers in the master docket, No. 1:17-MD-2804. All filings discussed in this CMO shall be filed electronically in the master MDL docket. Any document that pertains to one or multiple specific cases shall be electronically filed in each case docket *and* in the master MDL docket. Electronic case filing of a document, other than an initial pleading, in the master docket shall be deemed to constitute proper service on all parties. Discovery and other documents not filed with the Court shall be served by electronic mail on the appropriate Lead and Liaison Counsel and other appropriate counsel as set forth below in paragraph 9.c.

5. **COMMUNICATIONS WITH THE COURT**

Unless otherwise ordered by the Court, all substantive communications with the Court shall be filed. Excepted from this rule is correspondence with the Special Masters and discovery disputes, which are governed by paragraph 9.o below.

6. **PLEADINGS AND MOTIONS**

a. **Direct Filing.** In order to eliminate delays associated with transfer to this Court of cases filed in or removed to other federal district courts, any Plaintiff whose case would be subject to transfer to these MDL proceedings may file its case directly in this District. Direct filing shall not constitute a waiver of any party's contention that jurisdiction or venue is improper or that the action should be dismissed or transferred. Direct filing shall not impact the choice of law to be applied in the case.

At the conclusion of pretrial proceedings, should the parties agree that a case filed directly in the MDL proceedings should be transferred and the district to which it should be transferred, the parties will jointly advise the Court of the district to which the case should be transferred at the appropriate time. Should the parties disagree as to the district to which a case should be transferred, nothing in this Order precludes any party from filing a motion to transfer pursuant to 28 U.S.C. §1404(a) or §1406 at the conclusion of pretrial proceedings.

b. **Amendment of Pleadings and Addition of Parties.** In cases other than those mentioned in paragraphs 2 and 3, Plaintiffs shall file any amended pleading, including any amendment to add a party to a case, **no later than Friday, May 25, 2018.** After that date, no complaint shall be amended by Plaintiffs to add a party or otherwise, absent leave of Court or stipulation of the parties. The deadline for Defendants to add a party without leave of Court shall be **45 days before the close of fact discovery** applicable to a particular case.

c. **Service of Summons and Complaint.** Defendants are encouraged to avoid unnecessary expenses associated with serving the summons and, absent good cause, shall grant requests to waive service pursuant to Fed. R. Civ. P. 4(d)(1).

d. Plaintiffs shall not name as a Defendant, nor seek to serve, any entity as to which Plaintiffs lack a good faith basis to assert that the entity is subject to personal jurisdiction in this Court. Notwithstanding the foregoing, waiving service of a summons does not waive any objection to personal jurisdiction or to venue. Fed. R. Civ. P. 4(d)(5). **No later than Wednesday, April 25, 2018**, each Defendant shall file a notice in the master docket that attaches a proper form of a waiver request and a designated person to electronically accept the same. Such waiver requests shall be timely executed and returned to the requesting party for filing with the Court. The Court previously tolled the deadline to achieve service of the summons and complaints through **May 18, 2018**. The Court expects the Plaintiffs in all filed cases as of the date of this Order to effectuate service by **Wednesday, July 18, 2018**. Service on a foreign corporation is suspended until further order of the Court.

e. **Voluntary Dismissal.** At this point, with the parties actively engaged in working towards global resolution, including through a litigation track, dismissal without prejudice of Trial Track cases or cases designated for motion to dismiss briefing has a potentially detrimental effect on the Court, the parties, and the MDL process. Accordingly, because the timeframe for responsive pleading has been extended beyond that ordinarily contemplated by Fed. R. Civ. P. 41(a)(1)(A)(i), and notwithstanding the fact that Defendants may not yet have answered, any voluntary dismissals pending in this MDL as of the date of this Order or filed hereafter that would result in the dismissal of any such action against all named Defendants shall require leave of Court.

f. **General Motions and Briefing Requirements.** Except as otherwise provided herein, all motions and briefs shall conform to Local Rule 7.1. All motions on behalf of Plaintiffs or PEC or Plaintiffs' Steering Committee must be signed by Plaintiffs' Lead Counsel. All motions on behalf of all Defendants or a Defendants' Steering Committee must be signed by Lead Counsel for each moving Defendant.

g. **Motions.** No party may file any motion not expressly authorized by this Order absent further Order of this Court or express agreement of the parties. However, nothing in this Order limits the right of a State Attorney General to seek remand of any case brought by the Attorney General that is removed to the MDL. The Court shall decide any such motion on the merits.

7. **COORDINATION WITH STATE COURT PROCEEDINGS**

The Court acknowledges it has no jurisdiction over related State court proceedings. To achieve the full benefits and efficiencies of the MDL proceedings, however, this Court intends to coordinate with State courts presiding over related cases to the greatest extent possible, in order to avoid unnecessary duplication and inconsistency. This includes efforts at coordination of written discovery and deposition protocols and cross-noticing of depositions. The Court appoints Special Master Yanni to oversee these efforts.

8. **PRESERVATION**

a. All parties and their counsel are reminded of their duty, consistent with the Federal Rules of Civil Procedure, to take reasonable measures to preserve documents, electronically stored information ("ESI"), and things that are potentially relevant.

b. The parties will meet and confer regarding a procedure for directing third-party records custodians to preserve records.

9. PRELIMINARY DISCOVERY PLAN AND PROCEDURES

a. **Discovery Under the Plan.** No party may conduct any discovery of another party in this MDL proceeding not expressly authorized by this Order absent further Order of this Court or express agreement of the parties.

b. **Waiver of Initial Disclosures.** For all cases in the MDL proceedings, the parties are relieved from complying with the requirements of Fed. R. Civ. P. 26(a)(1) unless otherwise directed by the Court.

c. **Service of Discovery.** Unless otherwise directed by this Court, the parties shall serve all papers that are not to be filed with the Court, including, but not limited to, discovery requests or responses, deposition notices, and certificates of service thereof, by electronic mail on Plaintiffs' Liaison Counsel and Defendant's Liaison Counsel. Such papers are not to be filed with the Clerk, nor are courtesy copies to be delivered to the Court, except when specifically ordered by the Court or to the extent needed in connection with a motion, and only in accordance with the protective order governing the MDL proceedings. Where a paper is applicable to all cases or substantially all cases, or such categories of cases as may be defined in subsequent Orders, Plaintiffs' Liaison Counsel also shall electronically serve such paper on counsel of record for the individual Plaintiff(s) to whom the paper is applicable. Where a paper to be served by a Defendant is applicable to a particular case, Defendants' Liaison Counsel shall electronically serve such paper on the counsel of record for the individual Plaintiff(s) in that case as well as Plaintiffs' Liaison Counsel.

All discovery directed to Defendants and non-party witnesses on behalf of Plaintiffs shall be undertaken by, or under the direction of, the PEC on behalf of all Plaintiffs with cases in these MDL proceedings.

d. **Protective Order.** Disclosure and discovery in this proceeding may involve production of confidential, proprietary, and private information for which special protection from public disclosure and from any purpose other than prosecuting this litigation would be warranted, including insurance information discussed in paragraph 3.d. The parties will meet and confer and submit to the Court, **no later than Monday, April 30, 2018**, a proposed Protective Order, binding on all parties and counsel, to ensure the protection of confidential information, including any HIPAA-protected information.

e. **Format of Production.** The parties will meet and confer and submit to the Court, **no later than Monday, April 30, 2018**, a proposed Document Production Protocol governing the format of production of documents.

f. **Deposition Protocol.** The parties will meet and confer and submit to the Court, **no later than Monday, May 21, 2019**, a protocol governing depositions, including with respect to the scheduling, noticing, taking, and recording of depositions, and procedures to ensure that, absent agreement or court order, a witness will not be deposed more than once across any state or federal cases.

g. **Assertion of Privilege.** Any party that withholds the production of requested documents or materials on the ground of any privilege or application of the work-product doctrine must provide a Privilege Log. Each Privilege Log shall describe each document or thing for which a privilege or the work product doctrine is asserted in sufficient detail to reasonably permit the party seeking discovery to assess whether to dispute any such assertion. This will include but is not limited to information regarding the document's subject, date, author, and all recipients, the specific privilege asserted, and the factual basis for the privilege. Each party withholding materials shall provide opposing counsel a copy of the Privilege Log within **45 days**

after the production, absent agreement of the parties. If a partial production is made, the party shall produce a privilege log relating to such partial production. The parties will raise privilege issues with Magistrate Judge Ruiz, in accord with the procedures set out in paragraph 9.0, as soon as reasonably possible.

h. **Ex Parte Communications with Treating or Prescribing Healthcare Providers.** Absent further order of the Court, contact with a non-party treating or prescribing healthcare provider for any patient whose medical care or treatment is the basis of any Plaintiff's claims shall be governed by the relevant procedural rules in the jurisdiction in which the healthcare provider resides. The parties reserve the right to seek a further order governing ex parte communications with such non-party healthcare providers.

i. **Fact Sheets.** The parties shall meet and confer and submit to the Court, **no later than Monday, April 30, 2018**, a proposed Order regarding Plaintiff Fact Sheets and Defendant Fact Sheets. The fact sheets shall apply to each case within MDL 2804, and in all other cases that become part of this MDL by virtue of being filed in, removed to, or transferred to this Court. The parties may agree to an exception regarding whether they will produce Fact Sheets, or their content, with regard to Track One Cases.

j. **Joint Records Collection.** The parties are directed to confer and reach an agreement regarding the selection of one or more Joint Custodian(s) to collect and retain certain medical or other records from any third-party designated as a record custodian by either Plaintiffs or Defendants and present to the Court a protocol and Stipulated Joint Records Collection Order **no later than Monday, April 30, 2018**.

k. **Prior Document Disclosures.**

i. Upon entry of this Order, all documents, including ESI, that were previously produced by any Defendant in *City of Chicago v. Purdue Pharma L.P.*, Case No. 14-CV-04361 (N.D. Ill.), shall be deemed produced to all Plaintiffs in MDL 2804 and shall be made immediately available to the PEC by any parties or counsel in possession of same, at no cost to the party or counsel in possession.

ii. **No later than Monday, June 11, 2018**, all Defendants shall review documents previously produced pursuant to any civil investigation, litigation, and/or administrative action by federal (including Congressional), state, or local government entities involving the marketing or distribution of opioids and shall produce to the PEC non-privileged documents relevant to the claims in this MDL proceeding. Defendants shall engage in rolling production of previously-produced documents during this 61-day period, and shall engage in rolling production of privilege logs and lodging of objections.

iii. After Defendants complete the foregoing document productions, to the extent the PEC believes there are other documents that were produced by a Defendant in another proceeding that are discoverable in this proceeding, the PEC shall notify the Defendant and identify the specific document(s) and basis for requesting production, and the parties shall meet and confer to attempt to resolve the issue. To the extent the parties are unable to resolve the issue, the PEC shall bear the burden to demonstrate to the Court that the document(s) should be produced in this proceeding.

iv. Unless and until other arrangements are made by this Court regarding these specific materials, and in the interests of expediting discovery, Plaintiffs in MDL 2804 will be subject to any pre-existing Protective Orders or confidentiality agreements

governing this material. As such, at this time, review by Plaintiffs and their experts of discovery that has been produced in other cases and which is deemed produced in this MDL is subject to any Protective Orders or confidentiality agreements entered in those cases. The entry of a Protective Order in this MDL proceeding, however, will supersede any pre-existing Protective Order.

1. **Written Discovery.**

i. Any written discovery served on a Defendant pursuant to paragraph 3 above shall be coordinated and served by the PEC. Absent leave of Court, the PEC may serve up to 35 Requests for Production and up to 35 Interrogatories on each Defendant Family in cases in Track One and subsequent Case Tracks identified pursuant to paragraph

3. For purposes of this requirement, a “Defendant Family” shall consist of all corporate affiliates that are named as a Defendant in any action that is part of this MDL. For illustration purposes only, Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company Inc. shall be treated as a single Defendant Family.

ii. Each group of Defendants named in a case (e.g., the Manufacturer Defendants, the Distributor Defendants, and the Retail Pharmacy Defendants) may serve up to 35 Requests for Production and up to 35 Interrogatories on each Plaintiff in cases in Track One and subsequent Case Tracks identified pursuant to paragraph 3.

iii. **No later than, Monday, July 16, 2018**, each Plaintiff in cases in Track One that alleges money damages based upon unnecessary prescriptions shall identify: (a) the prescriptions that each Plaintiff asserts were medically unnecessary or medically inappropriate, to whom they were written, and whether Plaintiff reimbursed for them; (b) the physicians or healthcare providers who wrote the prescriptions; and (c) Plaintiff’s basis for

identifying the prescriptions that it asserts are medically unnecessary or medically inappropriate.

m. **Third-Party Discovery.** The parties may conduct appropriate third-party discovery in Track One cases, including discovery to identify the information discussed in paragraph l.iii. Any party intending to serve third-party discovery shall comply with Fed. R. Civ. P. 45(a)(4).

n. **Extension of Discovery Deadlines.** Nothing in this Order shall be interpreted to restrict the ability of the parties to move, separately or (preferably) jointly, for an extension of discovery deadlines as permitted by the Rules. Please note that the granting of an extension of any discovery deadline shall not change the trial date, and the Court does not intend to move the trial date of the Track One case(s). Should any of the deadlines set forth above become infeasible as a result of an unexpected technical or similar matter, the responding party shall provide advance notice and an estimated date for the response. If, after meeting and conferring in good faith, the receiving party objects to any modified date, it may seek a conference with the Court.

o. **Discovery Dispute Resolution.** Counsel shall comply with Local Rule 37.1. Specifically, the parties shall resolve discovery disputes by following these steps: (1) good faith resolution efforts by counsel; (2) telephone conference-call to Judge Polster's chambers, at which time the Court will direct the parties how and when they will present their issues to either Judge Polster or Magistrate Judge Ruiz; (3) if requested by the Court, position letters (normally not to exceed 3 pages); and (4) if required, discovery motion pursuant to Fed. R. Civ. P. 37.

p. **Filing of Discovery Materials.** No discovery materials shall be filed without leave of Court, except as necessary to support dispositive motions. If a party intends to

rely on deposition testimony in support of a motion, the Court prefers the filing of the entire deposition in condensed form rather than excerpts, unless the party truly believes that excerpts are sufficient. If any other party believes the excerpts offered are not sufficient, that party is free to file the entire deposition in condensed form. In any event, discovery material submitted in support of a party's position shall be filed at the same time as that party's memorandum setting forth its position.

10. EXPERT REPORTS AND EXPERT MATERIALS

a. The designation of experts whose opinions may be submitted at trial must be accompanied by a report that complies with Fed. R. Civ. P. 26(a)(2)(B). The report must be provided contemporaneously with the expert designation. All parties' experts whose opinions may be submitted at trial shall be subject to deposition as directed in Fed. R. Civ. P. 26(b)(4)(A) prior to the close of expert discovery.

b. Unless otherwise stipulated or ordered by the Court, each disclosed expert will produce his or her final report pursuant to and consistent with Fed. R. Civ. P. 26(a)(2)(B), together with identification of all documents that the expert has considered in preparing and/or rendering the expert's opinion. No other documents relating to expert reports will be produced, provided, however, that nothing in this order is intended to bar discovery of documents that are otherwise discoverable from a party or third party outside of the context of expert discovery. Consistent with Fed. R. Civ. P. 26(b)(4), no party will seek discovery of any experts' notes, drafts of expert reports, or communications with counsel, provided, however, that counsel may serve discovery or inquire at a deposition about any facts, data, or assumptions provided to the expert by counsel and upon which such expert is relying in expressing the expert's opinions. Each party also agrees to bear its own expert costs.

11. SUBSEQUENT TRIAL SETTINGS

The parties shall meet and confer to discuss pretrial and trial schedules for subsequent trial settings, including as to cases that may be remanded to transferor courts for trial. The parties shall inform the Court if a proposed trial schedule would result in overlapping trial settings.

12. MOTIONS FOR REMAND

In accord with paragraph 6.f, the Court will adopt a procedure, based on input from the parties, to efficiently address the filing and briefing of motions for remand at an appropriate time in the MDL proceedings.

13. REGULAR TELEPHONIC STATUS CONFERENCES

The Court will hold regularly-scheduled telephonic status conferences, on roughly a biweekly basis. Lead and Liaison Counsel for Plaintiffs and Defendants shall confer before each status conference and submit a joint status report three (3) business days before the conference. This joint report should include: (a) a list of expected participants, (b) a summary of resolution discussions or efforts conducted since the last status conference; (c) a summary of discovery conducted since the last status conference; (d) a summary of any pending motions; (e) updates about related state cases; (f) any scheduling issues or other issues that the parties wish to raise with the Court; and (g) if the parties have differing views on issues raised with the Court, a brief statement of their respective positions on these issues. The first such status conference shall be on **Wednesday, April 18, 2018 at noon Eastern Time**, and the second shall be on **Wednesday, May 2, 2018 at noon Eastern Time**. A call-in number will be provided.

14. CONDUCT

Pursuant to the Statement on Professionalism issued by the Supreme Court of Ohio on February 3, 1997, counsel are directed to be courteous and civil in all oral and written

communications with each other and the Court. Submissions that do not conform to this standard will be rejected. Nothing in this Order precludes the Court from entering sanctions against a party or counsel if warranted.

IT IS SO ORDERED.

/s/ Dan Aaron Polster

DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE

Dated: April 11, 2018

Exhibit 3

In re Nat'l Prescription Opiate Litig., No. MDL 2804,
2018 WL 6628898 (N.D. Ohio Dec. 19, 2018)

In re National Prescription Opiate Litigation, Not Reported in Fed. Supp. (2018)

2018 WL 6628898, RICO Bus.Disp.Guide 13,115

 KeyCite Yellow Flag - Negative Treatment
Distinguished by [Goff v. Nationwide Mutual Insurance Company](#),
S.D.Ohio, September 30, 2019

2018 WL 6628898

United States District Court, N.D. Ohio, Eastern
Division.

IN RE: NATIONAL PRESCRIPTION OPIATE
LITIGATION This Document Relates To: The
County of Summit, Ohio, et al. v. Purdue Pharma
L.P., et al., Case No. 18-op-45090

MDL 2804
|
Case No. 1:17-md-2804
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Signed 12/15/2018
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Filed 12/19/2018

OPINION AND ORDER

DAN AARON POLSTER, UNITED STATES
DISTRICT JUDGE

*1 This matter is before the Court upon the Report and Recommendation ("R&R") of the United States Magistrate Judge. **Doc. #: 1025** (hereinafter cited as "R&R"). On November 2, 2018 Manufacturer, Distributor, and Retail Pharmacy Defendants and Plaintiffs all filed Objections to various portions of the R&R. Doc. #: 1082, 1079, 1078, and 1080. On November 12, 2018 Plaintiffs and Defendants filed Responses to the Objections. Doc. #: 1115 and 1116. Upon a *de novo* review of the record, and for the reasons set forth below, the Court **ADOPTS IN PART** and **REJECTS IN PART** the Report and Recommendation.

The District Court reviews proper objections pursuant to its duty under [Federal Rule of Civil Procedure 72\(b\)](#). [Fed. R. Civ. P. 72\(b\)](#) ("The district judge must determine *de*

novo any part of the magistrate judge's disposition that has been properly objected to.") In a footnote, Manufacturer Defendants purport to object to "the entirety of the R&R." Doc #: 1082 at n.1. This objection is not proper insofar as it does not include any bases or in or support from legal authority. Therefore, as there are no proper objections to the facts or procedural history, the Court adopts the facts and procedural history as stated in the R&R. Further, there are no objections to the R&R with respect to the following sections:

- Section III.B. Preemption
- Section III.H. Count Eight: Fraud
- Section III.L. Statewide Concern Doctrine
- Section III.M. Article III Standing²

The Court presumes the parties are satisfied with these determinations and adopts the R&R with respect to these sections. "Any further review by this Court would be a duplicative and inefficient use of the Court's limited resources." [Graziano v. Nesco Serv. Co.](#), No. 1:09 CV 2661, 2011 WL 1131557, at *1 (N.D. Ohio Mar. 29, 2011) (citing  [Thomas v. Arn](#), 474 U.S. 140 (1985);  [Howard v. Secretary of Health and Human Services](#), 932 F.2d 505 (6th Cir.1991);  [United States v. Walters](#), 638 F.2d 947 (6th Cir.1981)).

As an initial matter, Retail Pharmacy Defendants have asked the Court to clarify that the claims brought against them are only brought in their capacity as distributors, not as dispensers. See Doc. #: 1078 at 2. The Court understands that Plaintiffs have disclaimed any cause of action against Retail Pharmacies in their capacity as retailers or dispensers of opioids, see Doc. #: 654 at 75 n.47, and thus considers the parties' arguments while keeping in mind that the Retail Pharmacies may only be held liable as distributors.

A. Tolling of the Statute of Limitations

*2 The R&R concluded that Plaintiffs have alleged sufficient facts "to raise a plausible inference that the applicable limitations periods are subject to tolling." R&R at 55-56. Manufacturer Defendants object, stating that Plaintiffs' Complaint indicates that they knew or should

In re National Prescription Opiate Litigation, Not Reported in Fed. Supp. (2018)

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have known of both the Manufacturers' marketing practices and the costs Plaintiffs were incurring. Defendants argue that it follows that Plaintiffs, by their own allegations, did not act with sufficient diligence to support a fraudulent concealment theory. In addition to tolling under a fraudulent concealment theory, Plaintiffs also assert that the continuing violations doctrine should be applied to save their claims from the relevant statute of limitations.

1. Fraudulent Concealment

The R&R correctly states that "resolving a motion to dismiss based on statute-of-limitations grounds is appropriate when the undisputed facts 'conclusively establish' the defense as a matter of law." R&R at 54 (citing *Estate of Barney v. PNC Bank*, 714 F.3d 920, 926 (6th Cir. 2013); *Cataldo v. U.S. Steel Corp.*, 676 F.3d 542, 547 (6th Cir. 2012), cert. denied, 568 U.S. 1157 (2013)). "In order for Plaintiff's delay in filing to be excused due to Defendants' fraudulent concealment, Plaintiff must affirmatively plead with particularity: '(1) wrongful concealment of their actions by the defendants; (2) failure of the plaintiff to discover the operative facts that are the basis of his cause of action within the limitations period; and (3) plaintiff's due diligence until discovery of the facts.' " *Reid v. Baker*, 499 F. App'x 520, 527 (6th Cir. 2012) (quoting *Dayco Corp. v. Goodyear Tire & Rubber Co.*, 523 F.2d 389, 394 (6th Cir.1975)). However, as the R&R also points out, "courts should not dismiss complaints on statute-of-limitations grounds when there are disputed factual questions relating to the accrual date." *Am. Premier Underwriters, Inc. v. Nat'l R.R. Passenger Corp.*, 839 F.3d 458, 464 (6th Cir. 2016) (citing as examples of disputed factual questions, "claims that the defendant fraudulently concealed facts, thereby preventing the plaintiff from learning of its injury...and complex issues about whether information in the plaintiff's possession sufficed to alert it of the claim").

Defendants' assertions that Plaintiffs were aware, at least since 2007, of their marketing practices and knew about the effects of the opioid crisis, effectively admitted in the Complaint,³ are insufficient to *conclusively establish* that any of Plaintiffs' claims are time-barred by the statute of limitations. If Plaintiffs relied solely on Defendants'

concealment of their marketing practices, Plaintiffs' assertion that the statutes of limitation were tolled due to fraudulent concealment would fail. However, Plaintiffs' allegations of fraudulent concealment do not rely solely on Defendants' alleged concealment of their marketing practices. Plaintiffs also allege that Defendants concealed their lack of cooperation with law enforcement and that they affirmatively misrepresented that they had satisfied their duty to report suspicious orders, concealing the fact that they had not done so. See Doc. #: 514 at 232-33 (hereinafter cited as "SAC").

Plaintiffs additionally point out that they could not have discovered "the nature, scope, and magnitude of Defendants' misconduct, and its full impact on Plaintiffs, and could not have acquired such knowledge earlier through the exercise of reasonable diligence," because until this Court ordered production of the ARCOS database in this litigation, Plaintiffs did not have access to that information. *Id.* at 233 (citing Doc. #: 233 at 6-7). Without access to the ARCOS data, Plaintiffs were forced to take Defendants at their word that they were complying with their obligations under consent decrees, statutes, and regulations. Plaintiffs inarguably knew about Defendants' marketing practices, but whether they had sufficient information, in the absence of the ARCOS data, to identify Defendants' alleged concealment and thus the scope or magnitude of Defendants' alleged misconduct is a disputed factual question.

2. Continuing Violations

*3 Plaintiffs also assert that the applicable statute of limitations should be tolled under the continuing violations doctrine. *Id.* at 231. In the Sixth Circuit, a "'continuous violation' exists if: (1) the defendants engage in continuing wrongful conduct; (2) injury to the plaintiffs accrues continuously; and (3) had the defendants at any time ceased their wrongful conduct, further injury would have been avoided." *Hensley v. City of Columbus*, 557 F.3d 693, 697 (6th Cir. 2009) (citing *Kuhnle Bros., Inc. v. County of Geauga*, 103 F.3d 516, 521 (6th Cir.1997)). Although Ohio courts are generally reluctant to apply the doctrine outside the Title VII context, "this doctrine is rooted in general principles of common law and is independent of any specific action." *Id.* Further, the Sixth Circuit has noted that "no opinion has articulated a

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principled reason why the continuing-violation doctrine should be limited to claims for deprivations of civil rights and employment discrimination.”  *Nat'l Parks Conservation Ass'n, Inc. v. Tennessee Valley Auth.*, 480 F.3d 410, 416–17 (6th Cir. 2007). “Courts have allowed the statute of limitations to be tolled [under the continuing violations framework] when...there is a ‘longstanding and demonstrable policy’ of the forbidden activity.”  *Ohio Midland, Inc. v. Ohio Dep't of Transp.*, 286 F. App'x 905, 912 (6th Cir. 2008) (citing  *Trzebuckowski v. City of Cleveland*, 319 F.3d 853, 857 (6th Cir.2003)).

Here, taking the factual allegations in the Complaint as true, Plaintiffs have alleged a longstanding and demonstrable policy of misrepresentations and omissions on the part of Defendants sufficient to demonstrate their engagement in continuing wrongful conduct. In addition, whether further injury could have been avoided had Defendants ceased this conduct is another disputed factual question. Therefore, the Court finds that Plaintiffs have alleged facts sufficient to raise a plausible inference that the applicable limitations periods are subject to tolling—under either a fraudulent concealment theory or a continuing violation theory—and that no claims should be dismissed on statute of limitations grounds at this early stage in the litigation.

B. RICO

After a lengthy discussion of RICO, the R&R concluded that Plaintiffs’ RICO claims should survive Defendants’ motions to dismiss. R&R at 11–44. “RICO was an aggressive initiative to supplement old remedies and develop new methods for fighting crime.”  *Sedima, SPRL v. Imrex Co., Inc.*, 473 U.S. 479, 498 (1985) (citing  *Russello v. United States*, 464 U.S. 16, 26–29 (1983)). In *Sedima*, the Supreme Court acknowledged the Second Circuit’s distress over the “extraordinary, if not outrageous,” uses to which civil RICO claims had been applied.  *Id.* at 499. “Instead of being used against mobsters and organized criminals, it had become a tool for everyday fraud cases brought against respected and legitimate enterprises.” *Id.* However, in reversing the 2nd Circuit, the *Sedima* Court observed:

...Congress wanted to reach both “legitimate” and “illegitimate” enterprises.  *United States v. Turkette*,

[452 U.S. 576 (1981)]. The former enjoy neither an inherent incapacity for criminal activity nor immunity from its consequences. The fact that § 1964(c) is used against respected businesses allegedly engaged in a pattern of specifically identified criminal conduct is hardly a sufficient reason for assuming that the provision is being misconstrued. Nor does it reveal the “ambiguity” discovered by the court below. “[T]he fact that RICO has been applied in situations not expressly anticipated by Congress does not demonstrate ambiguity. It demonstrates breadth.”  *Haroco, Inc. v. American National Bank & Trust Co. of Chicago*, [747 F.2d 384, 398 (1984)].

Id.

The RICO analysis is complicated because, “RICO’s civil-suit provision imposes two distinct but overlapping limitations on claimants—standing and proximate cause...[a]nd as a matter of RICO law, the two concepts overlap.”  *Trollinger v. Tyson Foods, Inc.*, 370 F.3d 602, 613 (6th Cir. 2004). Defendants object to the R&R’s conclusions regarding both “overlapping” limitations. Regarding standing, Defendants argue that Plaintiffs’ injuries are 1) not to Plaintiffs’ “business or property” as required by the statute, and 2) derivative of a third-party’s injuries (i.e. not direct). Regarding proximate cause, Defendants argue that Plaintiffs’ injuries are too remote to hold Defendants liable under RICO (i.e. not direct). Manufacturing Defendants succinctly summarize the way “directness” applies to RICO analysis.

*4 For standing to exist, an injury must be “direct” in the sense of being both (1) non-derivative of some third party’s injury (*the standing analysis*), See  *Trollinger*, 370 F.3d at 614; and (2) having an uninterrupted, direct, and not overly attenuated causal chain from conduct to injury (*the proximate cause analysis*), See  *Anza*, 547 U.S. at 457.

Doc. #: 1082 at 3 (citing  *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451 (2006)) (emphasis in original). “Because Congress modeled [the RICO] provision on

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similar language in the antitrust laws (§ 4 of the Clayton Act and § 7 of the Sherman Act) and because the antitrust laws have been interpreted to require that a private plaintiff show proximate cause in order to have standing to sue, RICO civil claims also require proximate cause.

Trollinger, 370 F.3d at 612 (citing *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 267-68 (1992);

Sedima, 473 U.S. at 496). Thus, although standing is a threshold issue, because proximate cause analysis is necessarily incorporated within the standing analysis, the Court begins with proximate cause.

claims of the indirectly injured would force courts to adopt complicated rules apportioning damages among plaintiffs removed at different levels of injury from the violative acts, to obviate the risk of multiple recoveries. And, finally, the need to grapple with these problems is simply unjustified by the general interest in deterring injurious conduct, since directly injured victims can generally be counted on to vindicate the law as private attorneys general, without any of the problems attendant upon suits by plaintiffs injured more remotely.

1. Proximate Cause

In *Holmes*, the Supreme Court described proximate cause as “the judicial tools used to limit a person’s responsibility for the consequences of that person’s own act,” and further stated “the notion of proximate cause reflects ‘ideas of what justice demands, or of what is administratively possible and convenient.’” 503 U.S. at 268 (quoting W. Keeton, D. Dobbs, R. Keeton, & D. Owen, *Prosser and Keeton on Law of Torts* § 41, p. 264 (5th ed. 1984)). In a RICO claim, “[t]he proximate-cause inquiry...requires careful consideration of the ‘relation between the injury asserted and the injurious conduct alleged.’” *Anza*, 547 U.S. at 462 (quoting *Holmes*, 503 U.S. at 268). “Though foreseeability is an element of the proximate cause analysis, it is distinct from the requirement of a direct injury.” *Perry v. Am. Tobacco Co.*, 324 F.3d 845, 850 (6th Cir. 2003) (citing *Holmes*, 503 U.S. at 268-69.). Additionally, the *Holmes* Court provided several reasons why “some direct relation between the injury asserted and the injurious conduct alleged” is so important to the proximate cause analysis.

Holmes, 503 U.S. at 268. The Court stated:

First, the less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff’s damages attributable to the violation, as distinct from other, independent, factors. Second, quite apart from problems of proving factual causation, recognizing

Id. at 269–70 (internal citations omitted). Thus, it is important to first carefully consider the relationship between the injury asserted by Plaintiffs and the alleged injurious conduct of Defendants and then further consider whether that relationship implicates any of the concerns highlighted by the *Holmes* Court.

*5 Plaintiffs allege that “RICO Marketing Defendants...conducted an association-in-fact enterprise...to unlawfully increase profits and revenues from the continued prescription and use of opioids for long-term chronic pain” thereby creating the opioid epidemic.⁴ SAC at 270. Plaintiffs further allege that RICO Supply Chain Defendants...formed an association-in-fact enterprise...for the purpose of increasing the quota for and profiting from the increased volume of opioid sales in the United States” thereby creating the opioid epidemic.⁵ It is important to note that Plaintiffs never expressly define what they mean by the term “opioid epidemic.” The term may reasonably refer to the massive rate of addiction, overdose, and death associated with taking opioids. See, e.g., *id.* at 214-15 (“Ohio is among the states hardest hit by the opioid epidemic....Overdose deaths have become the leading cause of death for Ohioans under the age of 55.”).

However, the term “opioid epidemic” may just as reasonably include black markets for diverted opioids. See, e.g., *id.* at 284 (“[Defendants’ violations] allowed the widespread diversion of prescription opioids out of appropriate medical channels and into the illicit drug market—causing the opioid epidemic.”); see also *id.* at 7

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(“The increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose and death [and] black markets for diverted prescription opioids.). Regarding their asserted injuries, however, Plaintiffs are more explicit. Plaintiffs expressly assert thirteen categories of damages. *See id.* at 285-86. Among these is, for example, the “costs associated with ...attempts to stop the flow of opioids into local communities.” *Id.*

Manufacturer Defendants argue that the chain of causation from conduct to injury is as follows:

- (i) a Manufacturer made deceptive claims in promoting its opioids (*the conduct*);
- (ii) some physicians were exposed to that Manufacturer’s claims; (iii) which caused some of those physicians to write medically inappropriate opioid prescriptions they would not have otherwise written; (iv) which caused some of their patients to decide to take opioids; (v) which caused some of those individuals to become addicted to opioids; (vi) which caused some of those addicted individuals to need additional medical treatment, to neglect or abuse their families, to lose their jobs, and/or to commit crimes; (vii) which caused Plaintiffs to expend additional resources on emergency services, and to lose revenue from a decreased working population and/or diminished property values (*the injury*).

Doc. #: 1082 at 9-10 (emphasis in original). However, Plaintiffs have alleged sufficient facts to support a far more direct chain of causation: (i) RICO Marketing Defendants made deceptive claims in promoting their opioids in order to sell more opioids than the legitimate medical market could support (*the conduct*); (ii) the excess opioids marketed by the RICO Marketing Defendants and distributed by the RICO Supply Chain Defendants were then diverted into an illicit, black market; (iii) Plaintiffs were forced to expend resources beyond what they had budgeted to attempt to stop the flow of the excess opioids into local communities and to bear the costs associated with cleaning them up. Under this potential chain of causation, the relationship between Plaintiffs’ injury and Defendants’ alleged conduct is less remote than prior Sixth Circuit precedent finding proximate cause, and is not too remote to support a finding of proximate cause here. *See, e.g.,* [Trollinger, 370 F.3d at 619](#) (finding proximate cause where Tyson “hired sufficient numbers of illegal aliens to impact the legal employees’ wages,” having an “impact on the bargained-for wage-scale,” which “allowed Tyson not to

compete with other businesses for unskilled labor,” and finally where “Tyson’s legal workers did not ‘choose’ to remain at Tyson for less money than other businesses offered”).

*6 Thus, it is incumbent upon the Court to consider whether any of the *Holmes* Court’s reasons for requiring directness are implicated. Here, Plaintiffs’ alleged damages are not speculative, but concrete and ascertainable. No other party can vindicate the law and deter Defendants’ alleged conduct because Plaintiffs’ asserted damages are not recoverable by any other party. Finally, there is no potential for—and thus no reason for the Court to have to adopt complicated rules to prevent—duplicative recoveries. As none of the *Holmes* concerns are implicated in this case, the Court finds that Plaintiffs have sufficiently alleged proximate cause for their RICO claims.

2. Standing

Having determined that Plaintiffs have alleged sufficient facts to find that they do not stand at too remote a distance to recover, the Court now turns to standing. [Title 18 of the U.S. Code, section 1964\(c\)](#), has been deemed the standing provision of RICO. It provides that “[a]ny person injured in his business or property by reason of a violation of section 1962 of this chapter may sue therefor...and shall recover threefold the damages he sustains and the cost of the suit, including reasonable attorney’s fee.” [18 U.S.C. § 1964\(c\)](#). The two operative portions of this section are the “business or property” limitation and the “by reason of” limitation.

“The ‘by reason of’ limitation...bundles together a variety of ‘judicial tools,’ some of which are traditionally employed to decide causation questions and some of which are employed to decide standing questions.”

[Trollinger, 370 F.3d at 613](#) (citing [Holmes, 503 U.S. at 268.](#)). As it pertains to standing, the “by reason of” limitation is used to analyze whether a plaintiff is asserting an injury that was borne directly by that plaintiff or whether the injury was “derivative or passed-on” to the plaintiff by some intermediate party. *See* [id. at 614.](#)

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a. The “by reason of” Limitation (Direct Versus Passed-On Injury)

Defendants claim that Plaintiffs’ asserted injuries are “necessarily derivative of harms to individual opioid users.” Doc. #: 1082 at 4. They state that “it is the opioid user who (if anyone) was directly harmed, and it is only as a result of this harm—in the aggregate—that Plaintiffs can claim to have experienced additional public expenditures, lost tax revenue, and diminished property values.” *Id.* Defendants cite *Perry* as a paradigmatic example from the Sixth Circuit of the distinction between derivative and non-derivative injuries. Defendants characterize *Perry* as follows: “Plaintiffs [in *Perry*] were individual insurance plan subscribers who alleged that because of the tobacco manufacturers’ conduct, they paid increased premiums to account for medical care provided to smokers in the same insurance pool.” *Id.* at 4-5 (citing  *Perry*, 324 F.3d at 847) (internal citations omitted).

Defendants’ characterization of *Perry* is correct, but *Perry* is factually distinct from this case. In *Perry*, tobacco users suffered smoking-related injuries which increased healthcare costs. That is where the similarities with the present case end. In *Perry*, the increased healthcare costs were borne by insurance companies who then passed-on those costs to individual insurance plan subscribers in the form of higher insurance premiums. The non-smoking individual subscribers then sued the tobacco companies for the costs passed-on to them by the insurance companies. See  *Perry*, 324 F.3d at 847. Thus, *Perry* represents a classic case of “passed-on” economic injury. Here, as described above, Plaintiffs have alleged a plausible claim that their injuries are the direct result of Defendants’ creation of an illicit opioid market within their communities.⁶ Plaintiffs’ asserted economic injuries are borne by them and not passed-on by any intermediate party standing less removed from Defendants’ actions.

*7 The tobacco cases, in general, are factually distinct from the present case for an additional reason. In the tobacco cases, no one asserted, nor could they have, that tobacco defendants created an “illicit cigarette market” the attendant consequences of which might have caused the government plaintiffs to expend their limited financial resources to mitigate. This “opioid epidemic as an illicit market” concept is an important distinction underlying many of Plaintiffs’ allegations. See, e.g., SAC at 150-51.

Therefore, assuming as it must that Plaintiffs can prove their allegations, the Court finds it plausible that Plaintiffs’ asserted injuries were directly caused “by reason of” Defendants’ injurious conduct.

b. The “business or property” Limitation

Even if Plaintiffs’ asserted injuries were proximately and directly caused “by reason of” Defendants’ alleged injurious conduct, Plaintiffs still may not bring a RICO claim if the injuries asserted were not to their “business or property.”  18 U.S.C. § 1964(c). As a general principal, “money, of course, is a form of property.”

 *Reiter v. Sonotone Corp.*, 442 U.S. 330, 338 (1979). It is also true that, “[a] person whose property is diminished by a payment of money wrongfully induced is injured in his property.”  *County of Oakland v. City of Detroit*, 866 F.2d 839, 845 (6th Cir. 1989) (quoting  *Chattanooga Foundry and Pipe Works v. City of Atlanta*, 203 U.S. 390, 396 (1906)). Plaintiffs assert thirteen categories of expenditures that they contend represent a substantial monetary loss, and are therefore an injury to their property. See SAC at 285. Defendants contend that none of the monetary costs asserted by Plaintiffs are the type of property injury anticipated (and thus permitted) by the RICO statute.

(i) Personal Injuries

The Sixth Circuit has held that “personal injuries and pecuniary losses flowing from those personal injuries fail to confer relief under  § 1964(c).”  *Jackson v. Sedgwick Claims Mgmt. Servs., Inc.*, 731 F.3d 556, 565-66 (6th Cir. 2013). “Courts interpreting RICO have remained faithful to this distinction [between non-redressable personal injury and redressable injury to property] by excluding damages ‘arising directly out of’ a personal injury, even though personal injuries often lead to monetary damages that would be sufficient to establish standing if the plaintiff alleged a non-personal injury.” *Id.* (emphasis added).

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The *Jackson* court's holding that RICO claims that allege damages "arising directly out of a personal injury" are not redressable adds another layer to the "directness" requirement summarized by Defendants above. As stated previously, Defendants explained two ways in which RICO allegations must be sufficiently direct to maintain a RICO claim. First, the relationship between the asserted injury and the alleged injurious conduct must have a *direct* causal connection. (the proximate cause analysis). And second, the asserted injury must also be borne *directly* by Plaintiffs and not passed-on to them by intermediate parties (the standing "by reason of" analysis). Under *Jackson*, there is an additional element of *directness* to consider—whether Plaintiffs' alleged injury arises *directly* out of a personal injury. While the first two analyses require closeness of the relationship between injury and injurious conduct, the *Jackson* analysis requires separation between personal injury and pecuniary losses that arise therefrom.

To determine what type of pecuniary losses arise directly out of personal injury, the Court first looks to the facts of *Jackson* itself. In *Jackson*, former employees who suffered personal injuries at work sued their employer for a RICO violation. They alleged that their employer's workers' compensation administrator and physician engaged in a fraudulent scheme to avoid paying workers' compensation benefits to them, causing them to suffer monetary losses (i.e. receiving less money from their personal injury claim than they felt they were entitled to). See *id.* at 561-62. The *Jackson* court rejected the plaintiffs' theory that their workers' compensation benefits created an intervening legal entitlement to money, which is property under RICO. See *id.* at 566. The *Jackson* court also cites several examples where other circuits have considered when a pecuniary harm arises directly out of a personal injury. See, e.g.,*id.* at 564 n.4. Reviewing these cases, the Court determines that their unifying character is that pecuniary losses "arise directly out of" a personal injury when the alleged RICO injury merely acts as an alternate theory for recovering damages otherwise available in a tort claim for personal injury and is asserted by the plaintiff him- or herself.⁷

*8 In other words, damages that result from a personal injury to a plaintiff (such as attorney fees, lost wages, lost workers' compensation benefits, or medical expenses), that are recoverable in a typical tort action are not recoverable in RICO, even if caused by a defendant's racketeering activity. These are costs that arise directly out of the plaintiff's personal injury, and are not injuries

to plaintiff's "business or property" under the statute.

Defendants contend that Plaintiffs are attempting to recover the pecuniary losses resulting directly from their addicted residents' physical injuries, citing *Jackson*. Plaintiffs respond that their economic losses are not pecuniary losses resulting from their addicted residents' personal injuries; rather, they are concrete economic losses to the cities and counties resulting directly from Defendants' relinquishment of their responsibility to maintain effective controls against diversion of Schedule II narcotics. See, e.g., 21 U.S.C. § 823(a)- (b).

Plaintiffs have the better argument. None of Plaintiffs' thirteen categories of costs arise directly out of a personal injury to Plaintiffs themselves. See Doc. #: 654 at 36-37 ("Plaintiffs' damages claims are not for personal injuries, but police and fire services, lost taxes, revenue and funding."). Even if *Jackson* can be read to preclude a RICO claim by a plaintiff who is tasked to protect the well-being of a third-party where the asserted economic harm is created by a personal injury to that third-party, it still does not follow that all thirteen categories of damages asserted by Plaintiffs arise directly out of such personal injuries. In that scenario, it would still be crucial to determine whether Plaintiffs' alleged injuries result directly from the personal injuries sustained by their citizens.

Plaintiffs assert the following injuries:

- a. Losses caused by the decrease in funding available for Plaintiffs' public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;
- b. Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;
- c. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;
- d. Costs associated with providing police officers, firefighters, and emergency and/or first responders with naloxone—an opioid antagonist used to block the deadly effects of opioids in the context of overdose;
- e. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;

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f. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;

g. Costs for providing treatment of infants born with opioid-related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy;

h. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;

*9 i. Costs associated with increased burden on Plaintiffs' judicial systems, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction;

j. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;

k. Loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiffs' communities;

l. Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and

m. Losses caused by diminished property values in the form of decreased business investment and tax revenue.

SAC at 285-286. Perhaps it can be said that items b and e above (the provision of medical treatment and emergency response services) arise directly out of the personal injury of the citizens because they are effectively claims to recoup the costs of medical expenses. However, there are other categories of costs, for example item h (the costs associated with "attempts to stop the flow of opioids into [Plaintiffs'] communities...[and] prevent the current opioid epidemic from spreading and worsening"), that cannot be said to arise directly out of Plaintiffs' residents' personal injuries. *Id.* Thus, under no reading of *Jackson* can it be maintained that *all* of Plaintiffs' asserted injuries arise directly out of a personal injury, and it is more

likely, in this Court's opinion, that most do not.

(ii) Sovereign Capacity

Finally, Defendants argue that regardless of the above, Plaintiffs cannot recover injury to their property to the extent they seek to recover costs associated with services provided in Plaintiffs' sovereign or quasi-sovereign capacities, which Defendants argue, accounts for the entirety of Plaintiffs' claimed injuries. Doc. #: 1082 at 6-7. Defendants implore the Court to follow the Ninth Circuit's holding in *Canyon County v. Syngenta Seeds, Inc.*, 519 F.3d 969 (9th Cir. 2008). Defendants claim that *Canyon County*'s holding that "money 'expended on public health care and law enforcement services' by a city or county does not constitute injury to 'business or property' under RICO" is applicable to the present case. See Doc. #: 1079 at 6 (quoting *Canyon County*, 519 F.3d at 971). Defendants point out that the Sixth Circuit has previously relied on *Canyon County* (albeit for its analysis of the proximate cause requirement of RICO and not for its "business or property" analysis) in *City of Cleveland v. Ameriquest Mort. Sec., Inc.*, 615 F.3d 496 (6th Cir. 2010). The R&R declined to follow *Canyon County*, however, stating that, "Defendants ...have not identified any Supreme Court or Sixth Circuit case directly on point with the facts of this case."

The R&R is correct because there has never been a case with facts analogous to those alleged by Plaintiffs here. It cannot be stressed strongly enough that the prescription opiates at issue in this case are **Schedule II controlled substances**.⁸ Plaintiffs have alleged a wanton disregard for public health and safety exhibited by Defendants with respect to their legal duty to try to prevent the diversion of prescription opioids. With the privilege of lawfully manufacturing and distributing Schedule II narcotics—and thus enjoying the profits therefrom—comes the obligation to monitor, report, and prevent downstream diversion of those drugs. See U.S.C. § 823(a)- (b). Plaintiffs allege that Defendants have intentionally turned a blind eye to orders of opiates they knew were suspicious, thereby flooding the legitimate medical market and creating a secondary "black" market at great profit to Defendants and at great cost to Plaintiffs.⁹ Plaintiffs must shoulder the

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responsibility for attempting to clean up the mess allegedly created by Defendants' misconduct.

***10** In *Canyon County*, the County brought a RICO claim against four defendant companies for "knowingly employ[ing] and/or harbor[ing] large numbers of illegal immigrants within Canyon County, in an 'Illegal Immigrant Hiring Scheme.' "  *Canyon County*, 519 F.3d at 972. The County claimed that it "paid millions of dollars for health care services and criminal justice services for the illegal immigrants who [were] employed by the defendants in violation of federal law." *Id.* Based on these facts, the Ninth Circuit concluded that "when a governmental body acts in its sovereign or quasi-sovereign capacity, seeking to enforce the laws or promote the public well-being, it cannot claim to have been 'injured in [its]...property' for RICO purposes based *solely* on the fact that it has spent money in order to act governmentally."  *Canyon County*, 519 F.3d at 976 (emphasis added). As stated above, neither the Sixth Circuit nor the Supreme Court have adopted the holding in *Canyon County*, and certainly not for the broad proposition that governmental entities are *barred* from seeking RICO claims for services provided in their sovereign or quasi-sovereign capacities. Not even *Canyon County* established such a bright-line rule. The *Canyon County* court held that governmental entities are not injured in their property based *solely* on the expenditure of money to act governmentally. Use of the word "solely" implies that governmental entities might be able to assert an injury to their property based on the expenditure of money plus something else, perhaps, for example, the assumption of a statutory burden relinquished by a defendant.

In this case, the scope and magnitude of the opioid crisis—the illicit drug market and attendant human suffering—allegedly created by Defendants have forced Plaintiffs to go far beyond what a governmental entity might ordinarily be expected to pay to enforce the laws or promote the general welfare. Plaintiffs have been forced to expend vast sums of money far exceeding their budgets to attempt to combat the opioid epidemic. The Court thus concludes that while Cities and Counties cannot recover ordinary costs of services provided in their capacity as a sovereign, Cities and Counties should be able to recover costs greatly in excess of the norm, so long as they can prove the costs were incurred due to Defendants' alleged RICO violations.

Additionally, the Ninth Circuit held in *Canyon County*

that governmental entities can, in fact, recover in RICO for the costs associated with doing business in the marketplace. *See, e.g., id.* ("government entities that have been overcharged in commercial transactions and thus deprived of their money can claim injury to their property.").

It is Defendants' position that *all* of Plaintiffs' costs responding to Defendants' alleged misconduct are sovereign or quasi-sovereign public services derivative of their residents' opioid problems, for which they cannot recover. *See Doc. #: 1082 at 7.* The Court disagrees. Certainly, some of Plaintiffs' alleged costs are costs associated with the ordinary provision of services to their constituents in their capacity as sovereigns. *See, e.g., SAC at 285* (asserting injury due to the provision of emergency first responder services). These costs cannot be recovered unless Plaintiffs can prove they go beyond the ordinary provision of those services. However, some of Plaintiffs' alleged costs are clearly associated with Plaintiffs' *participation in the marketplace*, and for those costs, Plaintiffs can undoubtedly recover. *See, e.g., id.* (asserting injury due to the costs associated with purchasing naloxone to prevent future fatal overdoses).

Therefore, under the broadest reading of Sixth Circuit precedent, the Court finds that Plaintiffs may recover damages based on the provision of governmental services in their capacity as a sovereign to the extent they can prove the asserted costs go beyond the ordinary cost of providing those services and are attributable to the alleged injurious conduct of Defendants. Under a more restrictive reading of *Jackson*, Plaintiffs still may recover those costs associated with preventing the flood of these narcotics into their communities, which do not directly arise from the personal injuries of their citizens (e.g. providing medical care, addiction treatment, etc.). Lastly, Plaintiffs have sufficiently alleged that at least some of their claimed injuries are recoverable under RICO due to Plaintiffs' participation in the marketplace. Thus, the Court concludes that it is not appropriate to dismiss the RICO claims at this early stage in the litigation.

C. Civil Conspiracy

***11** The R&R concluded that Plaintiffs sufficiently pled a claim for civil conspiracy. R&R at 95-98. Distributor Defendants object, stating that the Complaint "alleges no facts to support the assertion that Distributors participated

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in the marketing of opioids [or]...in applying or lobbying for increased opioid production quotas from DEA,...[and] no facts to support the claim that Distributors conspired not to report the unlawful distribution practices of their competitors to the authorities.” Doc. #: 1079 at 2-3 (emphasis removed). Pharmacy Defendants also object, arguing that to the extent a civil conspiracy is alleged through Defendants’ participation in industry groups, the Complaint is deficient with respect to the Retail Pharmacies, because it does not allege their participation in those groups.

The R&R correctly identifies the elements of a cognizable conspiracy claim as: “(1) a malicious combination; (2) two or more persons; (3) injury to person or property; and (4) existence of an unlawful act independent from the actual conspiracy”  *Hale v. Enerco Grp., Inc.*, 2011 WL 49545, at *5 (N.D. Ohio Jan. 5, 2011) (citation and internal quotation marks omitted). Distributor Defendants take exception to the R&R’s finding of independent unlawful acts. Pharmacy Defendants object to the R&R’s finding of a malicious combination. Defendants miss the forest for the trees.

Distributor Defendants characterize the R&R’s finding of unlawful acts as “(1) fraudulently marketing opioids; (2) fraudulently increasing the supply of opioids by seeking increased quotas; and (3) failing to report suspicious orders.” Doc #: 1079 at 2. This mischaracterizes the R&R’s actual finding that “the statutory public nuisance, Ohio RICO, and injury through criminal acts claims” would all suffice to “fulfill the underlying unlawful act element.” R&R at 96. The Court agrees that any of these claims is sufficient to satisfy the underlying unlawful act element.

Pharmacy Defendants assert that, because the Complaint fails to expressly allege their participation in industry groups such as the Healthcare Distribution Alliance and Pain Care Forum, that Plaintiffs failed to adequately plead a civil conspiracy claim, at least regarding them. However, the R&R did not rely on industry group participation to find a malicious combination. The R&R concluded that:

Pleading the existence of a malicious conspiracy requires “only a common understanding or design, even if tacit, to commit an unlawful act.”  *Gosden v. Louis*, 687 N.E.2d 481, 496-98 (Ohio Ct. App. 1996). “All that must be shown is that...the alleged coconspirator shared in the general conspiratorial

objective.”  *Aetna Cas. & Sur. Co. v. Leahy Const. Co., Inc.*, 219 F.3d 519, 538 (6th Cir. 2000) (citation and internal quotation marks omitted).

Id. at 97. In other words, the R&R concluded that even absent evidence of participation in industry groups, alleging a “shared conspiratorial objective” is sufficient to demonstrate a “malicious combination” and thus survive Pharmacy Defendants’ motion to dismiss. Plaintiffs allege “*all Defendants* took advantage of the industry structure, including end-running its internal checks and balances, to their collective advantage.” SAC at 229 (emphasis added). Additionally, with respect to Retail Pharmacy Defendants specifically, Plaintiffs assert, “instead of taking any meaningful action to stem the flow of opioids into communities, they continued to participate in the oversupply and profit from it.” *Id.* at 184. Thus, the R&R concluded, and this Court agrees, that Plaintiffs adequately pled that Defendants shared a general conspiratorial objective of expanding the opioid market and that there was a common understanding between all Defendants to disregard drug reporting obligations to effectuate that goal. Therefore, the Court adopts the R&R with respect to section III.K.

D. Abrogation of Common Law Claims Under the Ohio Products Liability Act

*12 The R&R concluded that Plaintiffs’ Statutory Public Nuisance and Negligence Claims are not abrogated by the Ohio Product Liability Act (“OPLA”).¹⁰ R&R at 58-60, 61-62. As further discussed below, the Court concurs with and adopts the R&R’s recommendation and reasoning with respect to these findings. However, the R&R also concluded that Plaintiffs’ Common Law Absolute Public Nuisance Claim is abrogated by the OPLA. *Id.* at 62-65. The Court disagrees.

1. Abrogation of the Common Law Public Nuisance Claims

The Ohio Product Liability Act,  *Ohio Rev. Code § 2307.71 et seq.*, was enacted in 1988. It was amended in 2005 and amended again in 2007. Despite the General

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Assembly's attempts to clarify the language and intent of the statute's definition of "product liability claim," the Court finds that the definition remains ambiguous, and thus reviews the legislative history pursuant to [Ohio Rev. Code § 1.49\(C\)](#) ("If a statute is ambiguous, the court, in determining the intention of the legislature, may consider among other matters:...The legislative history.").

The OPLA, at the time of its enactment, did not explicitly state that it was intended to supersede all common law theories of product liability. It was also ambiguous regarding whether it superseded common law claims seeking only economic loss damages. The Ohio Supreme Court attempted to clarify these ambiguities in two cases,

[Carrel v. Allied Prods. Corp.](#), 677 N.E.2d 795, 799 (1997) (holding that "the common-law action of negligent design survives the enactment of the Ohio Products Liability Act.") and [LaPuma v. Collinwood Concrete](#), 661 N.E.2d 714, 716 (Ohio 1996) (holding that "although a cause of action may concern a product, it is not a product liability claim within the purview of Ohio's product liability statutes unless it alleges damages other than economic ones, and that a failure to allege other than economic damages does not destroy the claim, but rather removes it from the purview of those statutes.").

In 2005, the General Assembly added the following provision to the OPLA ("the 2005 Amendment"): "[Sections 2307.71 to 2307.80 of the Revised Code](#) are intended to abrogate all common law product liability causes of action." 2004 Ohio Laws File 144 (Am. Sub. S.B. 80) (codified at [Ohio Rev. Code § 2307.71\(B\)](#)). The associated legislative history of the 2005 Amendment states:

The General Assembly declares its intent that the amendment made by this act to [section 2307.71 of the Revised Code](#) is *intended to supersede the holding of the Ohio Supreme Court in [Carrel v. Allied Products Corp.](#) (1997), 78 Ohio St.3d 284*, that the common law product liability cause of action of negligent design survives the enactment of the Ohio Product Liability Act, [sections 2307.71](#)

to [2307.80 of the Revised Code](#), and to abrogate all common law product liability causes of action.

*¹³ *Id.* (emphasis added). Notably, the General Assembly cited the *Carrel* holding while conspicuously omitting the contemporary *LaPuma* holding. The Court therefore interprets the General Assembly's inclusion of *Carrel* to imply the intentional exclusion and therefore the tacit acceptance of the Ohio Supreme Court's holding in *LaPuma*.

In 2007, the Ohio Legislature further amended section 2307.71(A)(13) of the OPLA ("the 2007 Amendment") to add the following to the definition of "product liability claim:"

"Product liability claim" *also includes* any public nuisance claim or cause of action at common law in which it is alleged that the design, manufacture, supply, marketing, distribution, promotion, advertising, labeling, or sale of a product unreasonably interferes with a right common to the general public.

2006 Ohio Laws File 198 (Am. Sub. S.B. 117) (emphasis added). The associated legislative history of the 2007 Amendment further states:

The General Assembly declares its intent that the amendments made by this act to [sections 2307.71](#) and [2307.73 of the Revised Code](#) are *not intended to be substantive but are intended to clarify the General Assembly's original intent* in enacting the Ohio Product Liability Act, [sections 2307.71 to 2307.80 of the Revised Code](#), as initially

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expressed in Section 3 of Am. Sub. S.B. 80 of the 125th General Assembly, to abrogate all common law product liability causes of action **including** common law public nuisance causes of action, regardless of how the claim is described, styled, captioned, characterized, or designated, including claims against a manufacturer or supplier for a public nuisance allegedly caused by a manufacturer's or supplier's product.

Id. (emphasis added). Senate Bill 80 of the 125th General Assembly (the 2005 Amendment) was a “tort reform” bill that was enacted to create limitations on various types of non-economic damages. See 2004 Ohio Laws File 144 (Am. Sub. S.B. 80). Both the 2005 and 2007 Amendments demonstrate the General Assembly’s intent to limit non-economic damages on all common law theories of product liability regardless of how the claim was characterized.

Throughout these amendments, however, the overarching substantive definition of a “product liability claim” has not changed much from the original 1988 OPLA definition. To fall within the statute’s definition a plaintiff’s product liability claim must 1) seek to recover compensatory damages 2) for death, physical injury to a person, emotional distress, or physical damage to property other than the product in question (*i.e.* “harm” as defined by the statute).¹¹ The subsequent amendments make clear that any civil action concerning liability for a product due to a defect in design, warning, or conformity—including any common law public nuisance or common law negligence claim, regardless of how styled—that 1) seeks to recover compensatory damages 2) for “harm” is abrogated by the OPLA. Conversely, a claim *not* seeking to recover compensatory damages or seeking to recover solely for “economic loss” (*i.e. not “harm”*) does not meet the definition of a product liability claim and is not abrogated by the OPLA. The OPLA is explicit that “Harm is not ‘economic loss,’ ” and “Economic Loss is not ‘harm.’ ”  [Ohio Rev. Code § 2307.71\(A\)\(2\) and \(7\).](#)

This reading of  [§ 2307.71\(A\)\(13\)](#) is consistent with the legislative intent, the holding in *LaPuma*, and with § 2307.72(C) which states:

*14 Any recovery of compensatory damages for economic loss based on a claim that is asserted in a civil action, other than a product liability claim, is not subject to sections 2307.71 to 2307.79 of the Revised Code, but may occur under the common law of this state or other applicable sections of the Revised Code.



[Ohio Rev. Code § 2307.72\(C\).](#)

Further, by defining a “product liability claim” in terms of damages, the OPLA does not provide for any form of equitable remedy.¹² To conclude that all public nuisance claims, including those seeking equitable remedies, are subsumed by the OPLA would effectively be a substantive change in the law in contravention of the General Assembly’s express intent that the amendment *not* be substantive. In other words, if all public nuisance claims, including those only seeking equitable relief, were abrogated by the OPLA, a party merely seeking an equitable remedy to stop a public nuisance would be forced instead to sue for compensatory damages under the OPLA, a result that appears completely at odds with the legislative intent to limit non-economic compensatory damages. Therefore, a claim seeking only equitable relief is not abrogated by the OPLA.

The R&R concluded that the 2007 Amendment added public nuisance claims as a second category of actions that fall under the definition of a product liability claim. See R&R at 58 n.37. In support of this conclusion, Defendants cite  [Mount Lemmon Fire Dist. v. Guido](#), 139 S. Ct. 22 (2018). See Doc. #: 1116 at 3. In *Mount Lemmon*, the Supreme Court interpreted Congress’ addition of a second sentence to the definition of “employer” under the ADEA.¹³ The Supreme Court held that the phrase “also means” adds a new category of employers to the ADEA’s reach. *Mount Lemmon* is factually inapposite, and the R&R’s conclusion is incorrect for two reasons. First, there is a substantive difference between the phrases “also means” and “also includes.” The term “means” is definitional, while “the term ‘including’ is not one of all-embracing definition, but connotes simply an illustrative application of the general principle.”  [In re Hartman](#), 443 N.E.2d 516, 517–18 (Ohio 1983) (quoting  [Federal Land Bank of](#)

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St. Paul v. Bismarck Lumber Co., 314 U.S. 95, 100 (1941)). In this case, the general principal is that to be a product liability claim, a plaintiff's cause of action must seek compensatory damages for harm. Thus, a public nuisance claim—to be “also include[d]” as a “product liability claim” under the OPLA—must likewise seek compensatory damages for harm.  [Ohio Rev. Code § 2307.71\(A\)\(13\)](#).

*15 Second, as the *Mount Lemmon* opinion points out, “Congress amended the ADEA to cover state and local governments.”  *Mount Lemmon*, 139 S. Ct. at 23. This amendment to the ADEA certainly amounts to—and was intended to be—an intentional, substantive change in the law. As highlighted above, however, the 2007 Amendment to the OPLA was not intended to be a substantive change.

Therefore, in light of the legislative history, the Court finds it at least plausible, if not likely, that the 2005 and 2007 Amendments to the OPLA intended to clarify the definition of “product liability claim” to mean “a claim or cause of action [*including* any common law negligence or public nuisance theory of product liability...] that is asserted in a civil action...that seeks to recover compensatory damages...for [harm]....” This definition is the most consistent with the statute, the legislative history, and the caselaw. See  *LaPuma v. Collinwood Concrete*, 661 N.E.2d 714, 716 (Ohio 1996) (“Failure to allege other than economic damages...removes it from the purview of [the OPLA].”) (intentionally not overruled by the 125th General Assembly);  *Volovetz v. Tremco Barrier Sols., Inc.*, 74 N.E.3d 743, 753 n.4 (Ohio Ct. App. Nov. 16, 2016) (“We recognize that a claim for purely economic loss is not included in the statutory definition of ‘product liability claim,’ and, consequently, a plaintiff with such a claim may pursue a common-law remedy.”); *Ohio v. Purdue Pharma*, Case No. 17 CI 261 (Ohio C.P. Aug. 22, 2018) (finding that the Plaintiff’s common law nuisance claim not seeking compensatory damages is not abrogated under the OPLA); *see also*, 76 Ohio Jur. 3d Claims Within Scope of Product Liability Act § 1 (“Ohio’s products liability statutes, by their plain language, neither cover nor abolish claims for purely economic loss caused by defective products.”).

Using this definition, Plaintiffs’ absolute public nuisance claim, at least insofar as it does not seek damages for harm,¹⁴ is not abrogated by the OPLA. Section III.E of the R&R is rejected to the extent it held that Plaintiffs’

absolute public nuisance claim is abrogated by the OPLA.

2. City of Akron’s Ability to Bring a Statutory Public Nuisance Claim

The R&R concluded that Plaintiffs’ statutory public nuisance claim was not abrogated. R&R at 62. No party objected to this conclusion, therefore the Court adopts the R&R with respect to this finding. The R&R further concluded that the City of Akron lacked standing to bring a statutory public nuisance claim, and that the County of Summit, which had standing, was not limited only to injunctive relief under the statute. The Pharmacy Defendants object to the R&R’s conclusion that [§ 4729.35 of the Ohio Revised Code](#) does not limit the remedy that can be sought under the statute to an injunction, and Plaintiffs object to the R&R’s conclusion that [§ 4729.35](#) limits who may maintain a nuisance action. The issue then, is whether [§ 4729.35](#) is limiting and if so, to what extent.

The operative statutes involved in Plaintiffs’ Statutory Public Nuisance Claim are:

[Ohio Rev. Code § 715.44\(A\)](#) (emphasis added):¹⁵

A municipal corporation may abate *any nuisance* and prosecute *in any court of competent jurisdiction*, any person who creates, continues, contributes to, or suffers such nuisance to exist.

[Ohio Rev. Code § 3767.03](#) (emphasis added):¹⁶

*16 *Whenever a nuisance exists*, the attorney general; the village solicitor, city director of law, or other similar chief legal officer of the municipal corporation *in which the nuisance exists*; the prosecuting attorney of the county in which the nuisance exists; the law director of a township that has adopted a limited home rule government under Chapter 504. of the Revised Code; or any person who is a citizen of the county in which the nuisance exists may bring an action in equity in the name of the state, upon the relation of the attorney general; the village solicitor, city director of law, or other similar chief legal officer of the municipal corporation; the prosecuting attorney; the township law director; or the person, to abate the nuisance and to perpetually enjoin the person maintaining the nuisance from further maintaining it.

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Ohio Rev. Code § 4729.35 (emphasis added):¹⁷

The violation...of any laws of Ohio or of the United States of America or of any rule of the board of pharmacy controlling the distribution of a drug of abuse...is hereby declared to...constitute a public nuisance. The attorney general, the prosecuting attorney of any county in which the offense was committed or in which the person committing the offense resides, or the state board of pharmacy may maintain an action in the name of the state **to enjoin such person** from engaging in such violation. Any action under this section shall be brought **in the common pleas court of the county where the offense occurred or the county where the alleged offender resides.**

If § 4729.35 had ended after the first sentence, there would be no question as among the three statutes that the City of Akron would have the authority to bring an action to abate a nuisance caused by the violation of applicable drug laws. However, the subsequent sentences of § 4729.35 can be read as either limiting or expanding (or both). Section 4729.35 is potentially limiting, for example, in that it does not also list city directors of law, chief legal officers of municipal corporation, or law directors of townships as parties that may maintain a nuisance action. It is also potentially limiting in that it only mentions injunctive relief rather than (or in addition to) relief in the form of abatement (or equitable relief generally). However, as Plaintiffs point out, § 4729.35 might be read as an expansion of § 3767.03 in that it additionally allows the state board of pharmacy and the prosecuting attorney of the county in which the alleged offender resides to maintain a nuisance action.¹⁸ It also provides jurisdiction in either the county where the offense occurred or the county where the alleged offender resides.

The R&R succinctly summarizes the applicable Ohio rule of statutory construction, “a court should construe various statutes in harmony unless their provisions are irreconcilably in conflict.” R&R at 65 (citing *Ohio Rev. Code* § 1.51;  *United Tel. Co. v. Limbach*, 643 N.E.2d 1129, 1131 (Ohio 1994)). In the event statutory provisions are irreconcilable, the special or local provision prevails. *See id.* Additionally, as before, the Court interprets the inclusion of certain elements in a statute to imply the intentional exclusion of others.

Here, § 4729.35 is a special or local provision. It is

irreconcilable with §§ 715.44(A) and 3767.03 because the plain language of these sections explicitly allows the chief legal officer of **any** municipal corporation, for example a city law director, to bring an action for abatement of **any** nuisance, whereas § 4729.35—at least implicitly—excludes a city law director from bringing a nuisance action for violations of the drug laws. Further, even a statutorily authorized party may only bring an action to enjoin such violations, not one for abatement.

*17 Thus, the Court concludes, as the R&R did, that the General Assembly’s inclusion of the attorney general, county prosecuting attorney, and state board of pharmacy in § 4729.35 implies the intentional exclusion of a city law director. Similarly, the Court concludes, though the R&R did not, that the General Assembly’s reference to “an action...to enjoin such person from engaging in such violation” implies the exclusion of other forms of relief. *Ohio Rev. Code* § 4729.35.

While it may not have been the General Assembly’s intent to limit the parties who can maintain a nuisance action or to limit the available relief, the Court declines to second guess the unambiguous text of the General Assembly’s statute. Further, because § 4729.35 is a special or local provision, irreconcilable with the more general provision, the Court reads § 4729.35 as an exception to the general provision. Therefore, the Court adopts the R&R’s conclusion that the City of Akron lacks standing to bring a statutory public nuisance claim but rejects the R&R’s conclusion that *Ohio Rev. Code* § 4729.35 does not expressly limit the categories of relief available for a nuisance claim to an injunction.

3. Abrogation of the Negligence Claim

The R&R concluded that the OPLA does not abrogate Plaintiffs’ negligence claims. R&R at 60. Distributor Defendants object to that determination. *See* Doc. #: 1079 at 12. As discussed above, the OPLA only abrogates civil actions that seek to recover compensatory damages for death, physical injury, or physical damage to property caused by a product. Distributor Defendants do not meaningfully develop any argument with respect to Plaintiffs’ negligence claim other than to cite several cases where courts purportedly dismissed various tort claims as preempted by the OPLA. The cases are all

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distinguishable.

Defendants cite *Chem. Solvents, Inc. v. Advantage Eng'g, Inc.*, 2011 WL 1326034 (N.D. Ohio Apr. 6, 2011). Regarding the plaintiff's negligence claim, the *Chem. Solvents* court first determined that "the Plaintiff [was] not saying that the product itself was defective." *Id.* at *13. The court then held, "Thus, this is not a 'products liability' claim, but a claim premised upon subsequent negligent actions by Advantage. Accordingly, the Court finds this claim is not preempted by the OPLA." *Id.* (citing *CCB Ohio LLC v. Chemque, Inc.*, 649 F. Supp. 2d 757, 763– 64 (S.D. Ohio 2009) ("Similarly, the Court finds actions for fraud and negligent misrepresentation as outside the scope of the OPLA's abrogation, as neither fit neatly into the definition of a 'common law product liability claim.' ")). Here, Plaintiffs likewise are not asserting that the opioid products themselves are defective, rather that Defendants negligently permitted (or even encouraged) diversion of those products.

Defendants also cite *McKinney v. Microsoft Corp.*, No. 1:10-CV-354, 2011 WL 13228141 (S.D. Ohio May 12, 2011). *McKinney* is a traditional products liability case where the plaintiff, in addition to his products liability claim under the OPLA, asserted a claim for negligent manufacture (i.e. a defective product claim), the exact type of claim considered by the General Assembly when it overruled *Carrel*. Plaintiffs' negligence claim in this case, again, does not assert that Defendants' opioids were defective.

Finally, Defendants turn to *Leen v. Wright Med. Tech., Inc.*, 2015 WL 5545064, at *2 (S.D. Ohio Sept. 18, 2015). In *Leen*, the plaintiff did not oppose the defendant's abrogation arguments in the motion to dismiss, so the court dismissed the common law negligence claim without considering the merits. *See id.* Therefore, based on this Court's analysis of the OPLA and the cases cited by Defendants, the Court adopts the R&R's conclusion that Plaintiffs' negligence claim is not abrogated.

*18 Defendants also assert that the R&R's reliance on *Cincinnati v. Beretta U.S.A. Corp.* is misplaced because, they claim, it was effectively overruled by the *General Assembly's amendments to the OPLA*. 768 N.E.2d 1136 (Ohio 2002); see Doc. #: 1079 at 14. Whether and to what extent the OPLA abrogates negligence claims is a separate and distinct question from whether there is a

common law duty to prevent or attempt to prevent the alleged negligent creation of an illicit secondary market.

As previously stated, the OPLA does not abrogate Plaintiffs' negligence claim, which seeks only relief from economic losses. However, even if the Court had found that Plaintiffs' negligence claim was abrogated, it does not follow that *Beretta*'s analysis of what constitutes a legal duty in Ohio is somehow flawed.¹⁹ Thus, *Beretta*'s discussion of Ohio common law duty is still relevant to the present case and is analyzed further below.

E. Negligence

The R&R concluded that Plaintiffs have pled sufficient facts to plausibly support their claims that Defendants owed them a duty of care, that their injuries were proximately and foreseeably caused by Defendants' failure to take reasonable steps to prevent the oversupply of opioids into Plaintiffs' communities, and that their claim is not barred by the economic loss doctrine. R&R at 74-85. Defendants object to the finding that they owed Plaintiffs any duty and the conclusion that the economic loss doctrine does not bar Plaintiffs' claim.

1. Duty of Care

Defendants make several objections to the R&R's analysis regarding the duty of care. "The existence of a duty of care, as an element of a negligence claim under Ohio law, depends on the foreseeability of the injury, and an injury is 'foreseeable' if the defendant knew or should have known that his act was likely to result in harm to someone." 70 Ohio Jur. 3d Negligence § 11 (citing *Bailey v. U.S.*, 115 F. Supp. 3d 882, 893 (N.D. Ohio 2015)).

The R&R concluded that "it was reasonably foreseeable that [Plaintiffs] would be forced to bear the public costs of increased harm from the over-prescription and oversupply of opioids in their communities if Defendants failed to implement and/or follow adequate controls in their marketing, distribution, and dispensing of opioids," and therefore, that "Plaintiffs have plausibly pleaded facts sufficient to establish that Defendants owed them a common law duty." R&R at 78-79.

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First, Manufacturer Defendants assert that to the extent they owe a statutory duty, it is owed to the U.S. Drug Enforcement Agency, not to plaintiffs. Doc. #: 1082 at 14. They also assert that they have no legal duty under [U.S.C. § 827](#) or [21 C.F.R. § 1301.74\(b\)](#) to monitor, report, or prevent downstream diversion. *Id.* These objections are not well-taken. The R&R expressly did not reach whether any Defendant owed a duty to Plaintiffs under the statutes or regulations. R&R at 79. It also did not address whether the statutes or regulations create a common law duty under a negligence *per se* theory. *Id.* at n.49. The R&R instead concluded that the common law duty pled by Plaintiffs was sufficient to support a negligence claim. *See* R&R at 79. This Court agrees.

***19** Distributor Defendants assert that the R&R “refus[ed] to confront a key duty question [(whether a duty, if one exists, flows to the County)] head on.” Doc. #:1079 at 14. They assert that “the R&R identified no Ohio case recognizing a common-law duty to *report or halt suspicious orders of controlled substances*,” and “even if there were a common-law duty to *report or halt suspicious orders*, no authority suggests that such a duty runs to the cities or counties.” *Id.* (emphasis added). The duty that Plaintiffs allege is not so narrow. Plaintiffs allege that Defendants, like all reasonably prudent persons, have a duty “to not expose Plaintiffs to an unreasonable risk of harm.” SAC at 312.

In reaching its conclusion on the duty of care, the R&R relies on *Cincinnati v. Beretta*. The R&R provides this summary:

In *Cincinnati v. Beretta*, the Ohio Supreme Court addressed the question of whether gun manufacturers owed a duty of care to a local government concerning harms caused by negligent manufacturing, marketing and distributing of firearms. *Beretta* involved allegations that the defendants failed to exercise sufficient control over the distribution of their guns, thereby creating an illegal secondary market in the weapons. The *Beretta* court concluded that the harms that

resulted from selling these weapons were foreseeable—that [Cincinnati was a foreseeable plaintiff. 768 N.E.2d at 1144](#). Plaintiffs argue that the harm caused by the marketing and distribution of opioids are similarly foreseeable.

R&R at 75-76. Here, taking Plaintiffs’ allegations as true, by failing to administer responsible distribution practices (many required by law), Defendants not only failed to prevent diversion, but affirmatively created an illegal, secondary opioid market. Opioids are Schedule II drugs. Despite Manufacturer Defendants’ marketing campaign to the contrary it is well known that opioids are highly addictive. When there is a flood of highly addictive drugs into a community it is foreseeable—to the point of being a foregone conclusion—that there will be a secondary, “black” market created for those drugs. It is also foreseeable that local governments will be responsible for combatting the creation of that market and mitigating its effects. Thus, the Court affirms the R&R’s conclusion that Defendants owe Plaintiffs a common law duty of care.

2. Economic Loss Doctrine

Defendants also object to the R&Rs conclusion that Plaintiffs’ negligence claim is not precluded by the economic loss doctrine. Defendants’ objections merely rehash arguments already made in their motions to dismiss. The R&R does a thorough analysis of the application of the economic loss rule, and this Court finds no fault with it. The R&R states:

The economic loss rule recognizes that the risk of consequential economic loss is something that the parties can allocate by agreement when they enter into a contract. This allocation of risk is not possible where, as here, the harm alleged is caused by involuntary interactions between a tortfeasor and a plaintiff. Thus, courts have noted that in cases involving only economic loss, the rule “will bar the tort claim if the duty arose only by contract.” [Campbell v. Krupp,](#)

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961 N.E.2d 205, 211 (Ohio Ct. App. 2011). By contrast, “the economic loss rule does not apply—and the plaintiff who suffered only economic damages can proceed in tort—if the defendant breached a duty that did not arise solely from a contract.” *Id.*; *see also*

Corporex, 835 N.E.2d at 705 (“When a duty in tort exists, a party may recover in tort. When a duty is premised entirely upon the terms of a contract, a party may recover based upon breach of contract.”); *Ineos USA LLC v. Furmanite Am., Inc.*, 2014 WL 5803042, at *6 (Ohio Ct. App. Nov. 10, 2014) (“[W]here a tort claim alleges that a duty was breached independent of the contract, the economic loss rule does not apply.”).

***20** R&R at 84 (citing *Corporex Dev. & Constr. Mgt., Inc. v. Shook, Inc.*, 835 N.E.2d 701 (Ohio 2005)). Thus, the Court concurs with and affirms the R&R’s analysis of the economic loss rule and its conclusion that it is not applicable to Plaintiffs’ tort claims.

G. Unjust Enrichment

The R&R concluded that Defendants’ motion to dismiss Plaintiffs’ Unjust Enrichment Claim should be denied. *See* R&R at 91-95. The issue at the heart of Defendants’ objections to the R&R’s conclusion is whether Plaintiffs conferred a benefit upon the Defendants. Defendants argue that “the rule in Ohio is that to show that a plaintiff conferred a benefit upon a defendant, an economic transaction must exist between the parties.” Doc. #: 1078 at 13 (internal quotations omitted) (citing *Ohio Edison Co. v. Direct Energy Bus., LLC*, No. 5:17-cv-746, 2017 WL 3174347 (N.D. Ohio July 26, 2017); *Caterpillar Fin. Servs. Corp. v. Harold Tatman & Sons Enters., Inc.*, 50 N.E.3d 955 (Ohio Ct. App. 2015); *In re Whirlpool Corp. Front-Loading Washer Prod. Liab. Litig.*, 684 F. Supp. 2d 942 (N.D. Ohio 2009)).

This is not the rule in Ohio. All the cases cited by Defendants refer back to one sentence in *Johnson v. Microsoft Corp.*: “*The facts in this case* demonstrate that no economic transaction occurred between Johnson and Microsoft, and, therefore, Johnson cannot establish that Microsoft retained any benefit ‘to which it is not justly entitled.’” 834 N.E.2d 791, 799 (Ohio 2005) (emphasis added) (citing *Keco Indus., Inc. v. Cincinnati & Suburban Bell Tel. Co.*, 141 N.E.2d 465 (Ohio 1957)). This holding is expressly limited to the facts of that case. *Johnson* does state the rule in Ohio, however. It provides: “The rule of law is that an *indirect purchaser* cannot assert a common-law claim for restitution and unjust enrichment against a defendant without establishing that a benefit had been conferred upon that defendant by the purchaser.” *Id.* (emphasis added).

F. The Injury Through Criminal Acts Objections
The R&R concluded that Defendants’ motion to dismiss Plaintiffs’ Injury Through Criminal Acts Claim should not be dismissed. R&R at 88-90. Defendants’ primary objection to this conclusion merely rehashes the argument initially made in their motions to dismiss: that they have not been convicted of a crime. Their objection cites no new facts or case law that were not already presented to and considered by Magistrate Judge Ruiz. Whether

Ohio Rev. Code § 2307.60(A)(1) requires an underlying conviction is a question this Court recently certified to the Ohio Supreme Court in *Buddenberg v. Weisack*, Case No. 1:18-cv-00522, 2018 WL 3159052 (N.D. Ohio June 28, 2018) (Polster, J.); *see also* 10/24/2018 Case Announcements, 2018-Ohio-4288 (available at <http://www.supremecourt.ohio.gov/ROD/docs/>) (accepting the certified question). In *Buddenberg*, this Court denied the defendants’ motion to dismiss and ordered, “Defendants may renew their challenge in the form of a motion for summary judgment after discovery and further research.” *Buddenberg*, 2018 WL 3159052 at *6. Nothing in any Defendants’ briefing convinces this Court that the same approach is not appropriate here. Therefore, the Court adopts the R&R with respect to Section III.I. Defendants’ objections are overruled.²⁰

***21** As Defendants are quick to point out, Plaintiffs do not claim to be purchasers of opioids, indirect or otherwise. *See, e.g.*, Doc. #: 1078 at 11 (“Plaintiffs do not allege that *they* purchased opioids from the Pharmacy Defendants.”). As such, the R&R rightly concludes that “Plaintiffs’ theory of recovery is not based on a financial transaction, therefore the claim is not barred by *Johnson*’s limiting indirect purchasers from maintaining unjust enrichment claims against parties other than those with whom they dealt directly.” R&R at 92.

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Plaintiffs' claim is that "Plaintiffs have conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper distribution practices." SAC at 328. According to Plaintiffs, Defendants' conduct allowed the diversion of opioids and thereby created a black market for their drugs. *See id.* at 7. This black market allowed Defendants to continue to ship large volumes of opioids into Plaintiffs' communities at great profit to Defendants and great expense to Plaintiffs. *See id.* at 328. Under Ohio law, "one is unjustly enriched if the retention of a benefit would be unjust, and one should not be allowed to profit or enrich himself or herself inequitably at another's expense." [18 Ohio Jur. 3d Contracts § 279](#). Therefore, for the reasons stated, Defendants' objections are overruled. The Court adopts Section III.J of the R&R.

Having considered Plaintiffs' Second Amended Complaint, Defendants' Motions to Dismiss, Plaintiffs' Omnibus Response, Defendants' Replies, Magistrate Judge Ruiz's Report and Recommendation, the parties' Objections to the R&R, and their Responses, Defendants' Motions to Dismiss, Doc. #: 491, 497, 499, are **DENIED** with the following exception: The City of Akron's Statutory Public Nuisance claim is dismissed for lack of standing under [Ohio Rev. Code § 4729.35](#). The County of Summit's Statutory Public Nuisance claim is limited to seeking injunctive relief.

It is accurate to describe the opioid epidemic as a man-made plague, twenty years in the making. The pain, death, and heartache it has wrought cannot be overstated. As this Court has previously stated, it is hard to find anyone in Ohio who does not have a family member, a

friend, a parent of a friend, or a child of a friend who has not been affected.

Plaintiffs have made very serious accusations, alleging that each of the defendant Manufacturers, Distributors, and Pharmacies bear part of the responsibility for this plague because of their action and inaction in manufacturing and distributing prescription opioids. Plaintiffs allege that Defendants have contributed to the addiction of millions of Americans to these prescription opioids and to the foreseeable result that many of those addicted would turn to street drugs.

While these allegations do not fit neatly into the legal theories chosen by Plaintiffs, they fit nevertheless. Whether Plaintiffs can prove any of these allegations remains to be seen, but this Court holds that they will have that opportunity.

The Court, thus having ruled on all of Defendants' Motions to Dismiss, orders Defendants to file their Answers to Plaintiffs' Corrected Second Amended Complaint, Doc. #: 514, no later than January 15, 2019.
IT IS SO ORDERED.

All Citations

Not Reported in Fed. Supp., 2018 WL 6628898, RICO Bus.Disp.Guide 13,115

Footnotes

¹ Defendant Noramco, Inc. states that it joined in Manufacturers' Motion to Dismiss "to the extent applicable," Doc. #: 499-1 at 1 n.2, and requests clarification that it is included among the moving Manufacturer Defendants and is entitled to all applicable relief. Doc. #: 1082 at 1 n.1. The Court clarifies that Noramco is included among the moving Manufacturer Defendants and is entitled to all applicable relief.

² Pharmacy Defendants, in their objections, mention Article III standing only briefly in a section dedicated to the RICO claims. *See* Doc. #: 1078 at 2-3. They mischaracterize the R&R's analysis of the Article III standing directness requirement, rehash arguments already made in their motion to dismiss, and then move on to address their RICO analysis concerns. The Court finds this objection without merit, and therefore it is overruled.

³ *See, e.g.*, Doc. #: 514 at 238 ("In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risks of addiction."); *see also* *Id.* at 212 ("the increase in fatal overdoses from prescription opioids has been widely

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publicized for years.”).

⁴ According to the Complaint, the RICO Marketing Defendants are “Purdue, Cephalon, Janssen, Endo, and Mallinckrodt.” See Doc. #: 514 at 270.

⁵ According to the Complaint, the RICO Supply Chain Defendants are “Purdue, Cephalon, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen” See Doc. #:514 at 279.

⁶ Plaintiffs allege that “Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market....All registrants—which includes all manufacturers and distributors of controlled substances—must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion.” Doc. #: 514 at 150-51 (citing 21 U.S.C. § 823(a)- (b); 21 C.F.R. § 1301.74).

⁷ Footnote 4 of the *Jackson* opinion cites the following exemplary cases: *Evans v. City of Chicago*, 434 F.3d 916 (7th Cir.2006) (false imprisonment causing loss of income not an injury to “business or property”); *Diaz v. Gates*, 420 F.3d 897 (9th Cir.2005) (*en banc*) (false imprisonment causing loss of employment and employment opportunity *is* an injury to “business or property”); *Hughes v. Tobacco Inst., Inc.*, 278 F.3d 417 (5th Cir.2001) (assault claim against tobacco company causing wrongful death of smoker not an injury to “business or property”); *Hamm v. Rhone-Poulenc Rorer Pharm., Inc.*, 187 F.3d 941 (8th Cir.1999) (retaliatory firing causing damage to reputation not an injury to “business or property”); *Bast v. Cohen, Dunn & Sinclair, PC*, 59 F.3d 492, 495 (4th Cir.1995) (surreptitiously recorded phone calls causing mental anguish not an injury to “business or property”); *Doe v. Roe*, 958 F.2d 763 (7th Cir.1992) (coercion into sexual relationship by attorney causing emotional harm not an injury to “business or property”); *Drake v. B.F. Goodrich Co.*, 782 F.2d 638, 644 (6th Cir.1986) (exposure to toxic chemicals during employment with defendant causing personal injuries not an injury to “business or property”).

⁸ “Since passage of the Comprehensive Drug Abuse Prevention and Control Act of 1970, *21 U.S.C. § 801 et seq.* (“CSA” or “Controlled Substances Act”), opioids have been regulated as controlled substances. As controlled substances, they are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs; hydrocodone and tapentadol were recently reclassified from Schedule III to Schedule II. Schedule II drugs have a high potential for abuse, and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence.” SAC at 16 n.5.

⁹ For example, Plaintiffs allege that “between 2012 and 2016, Summit County estimates that it spent roughly \$66 million on costs tied to the opioid crisis. Those costs are projected to add up to another \$89 million over the next five years, representing a total cost to the County of \$155 million over the ten year period “simply trying to keep up with the epidemic.’ ” Doc. #: 514 at 226.

¹⁰ Pharmacy Defendants argue, without any legal analysis, that Plaintiffs’ Unjust Enrichment Claim is abrogated by the OPLA. Doc. #: 1078 at 11. The R&R does not address whether Plaintiffs’ Unjust Enrichment Claim is abrogated by the OPLA, likely because the Pharmacies merely made a similarly undeveloped argument in their motion to dismiss, and only rehash them here. Due to the conspicuous lack of legal development in either Pharmacy Defendants’ Motion to Dismiss or Objections to the R&R, the Court finds this objection improper. Regardless, per the analysis below, the

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Court finds that Plaintiffs' Unjust Enrichment Claim is not abrogated by the OPLA.

- ¹¹ Section 2307.71(A)(13) of the OPLA also requires that the claim allegedly arise from any of:
(a) The design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product;
(b) Any warning or instruction, or lack of warning or instruction, associated with that product;
(c) Any failure of that product to conform to any relevant representation or warranty.  Ohio Rev. Code § 2307.71(A)(13).
- ¹² Defendants identify  section 2307.72(D)(1) as expressly carving out abatement relief for contamination of the environment as an indication that the OPLA supersedes all other forms of equitable relief. See Doc. #: 1116 at 4. However, a far more natural reading of this section is the carving out of all forms of relief for pollution of the environment from preemption by federal environmental protection laws and regulations.
- ¹³ Under the ADEA, "the term 'employer' means a person engaged in an industry affecting commerce who has twenty or more employees....The term *also means* (1) any agent of such a person, and (2) a State or political subdivision of a State...."  29 U.S.C. § 630(b) (emphasis added).
- ¹⁴ " 'Harm' means death, physical injury to person, serious emotional distress, or physical damage to property other than the product in question. Economic loss is not 'harm.' "  Ohio Rev. Code § 2307.71(A)(2).
- ¹⁵ Page's Ohio Revised Code Annotated, Title 7: *Municipal Corporations*, Chapter 715: *General Powers*, §§ 715.37-715.44: Health and Sanitation, § 715.44: Power to abate nuisance and prevent injury.
- ¹⁶ Page's Ohio Revised Code Annotated, Title 37: Health-Safety-Morals, Chapter 3767: Nuisances, §§ 3767.01- 3767.11: Disorderly houses, § 3767.03: Abatement of nuisance; bond.
- ¹⁷ Page's Ohio Revised Code Annotated, Title 47: Occupations-Professions, Chapter 4729: Pharmacists; Dangerous Drugs, §§ 4729.27-4729.46: Prohibitions, § 4729.35: Violations of drug laws as public nuisance.
- ¹⁸ As opposed to only the county prosecuting attorney in which the nuisance exists as allowed by section 3767.03.
- ¹⁹ The *Beretta* court determined that the defendants' negligent manufacturing, marketing, and distributing, and failure to exercise adequate control over the distribution of their products created an illegal, secondary market resulting in foreseeable injury and that from Defendants' perspective, the City of Cincinnati was a foreseeable plaintiff. See  *Beretta*, 768 N.E.2d at 1144.
- ²⁰ Should the Ohio Supreme Court rule that a criminal conviction is required, this claim will of course be dismissed.

Exhibit 4

In re Nat'l Prescription Opiate Litig., No. MDL 2804,
2020 WL 1669655 (N.D. Ohio Apr. 3, 2020)

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Only the Westlaw citation is currently available.
United States District Court, N.D. Ohio, Eastern
Division.

IN RE: NATIONAL PRESCRIPTION OPIATE
LITIGATION
This Document Relates To: West Boca Medical
Center, Inc. v. AmerisourceBergen Drug
Corporation, et al. 1:18-op-45530

MDL 2804

|
Case No. 1:17-md-2804

|
Signed April 3, 2020

Synopsis

Background: Hospital filed suit against pharmacies, distributors, and manufacturers of prescription opioid medications, claiming violations of Racketeer Influenced and Corrupt Organizations Act (RICO) and Florida's Deceptive And Unfair Trade Practices Act (FDUTPA) and asserting state law claims for misleading advertising, breach of implied warranty of fitness for particular purpose, common-law negligence, wanton negligence, negligence per se, negligent marketing, negligent distribution, nuisance, and unjust enrichment, by allegedly overstating benefits and downplaying risks of use of opioid painkillers, aggressively marketing opioids to physicians, and failing to monitor, investigate, refuse, and report suspicious orders of prescription opiates, thereby creating opioid crisis and extracting billions of dollars of revenue from addicted American public while tens of millions of dollars of injury were caused to hospitals. Defendants moved to dismiss for failure to state claim.

Holdings: The District Court, [Dan Aaron Polster, Jr.](#), held that:

sole proximate cause doctrine did not apply;
learned intermediary rule did not apply;
hospital sufficiently alleged proximate cause under RICO;

hospital sufficiently alleged standing under RICO;
investment injury was not sufficiently alleged for RICO claim;
public nuisance claim was sufficiently alleged;
FDUTPA claim was sufficiently alleged;
misleading advertising claim was sufficiently alleged;
common law negligence claim was sufficiently alleged;
wanton negligence claim was sufficiently alleged;
negligence per se claim was not actionable;
negligent marketing claim was not actionable;
negligent distribution claim was not actionable; and
unjust enrichment claim was sufficiently alleged.

Motions granted in part and denied in part.

Procedural Posture(s): Motion to Dismiss for Failure to State a Claim.

OPINION AND ORDER

[DAN AARON POLSTER](#), UNITED STATES DISTRICT JUDGE

*1 Before the Court are three separate motions to dismiss plaintiff West Boca Medical Center, Inc.'s ("West Boca," or the "Hospital") Complaint. Doc. #: 385.¹ Distributors,² Pharmacies,³ and Manufacturers⁴ each filed a group motion, seeking dismissal of West Boca's claims against them.⁵ Doc. #: 684-1 (Distributors); Doc. #: 686 (Pharmacies); Doc. #: 691 (Manufacturers). West Boca filed an omnibus response in opposition that addressed all

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three motions. Doc. #: 806. Distributors and Pharmacies filed replies in support of their respective motions. Doc. #: 887 (Distributors); Doc. #: 890 (Pharmacies). Manufacturers also filed a reply in support of their motion. Case No. 18-op-45530, Doc. #: 55.⁶

West Boca later filed a notice of supplemental authority, Doc. #: 911, and then (purportedly on behalf of all hospitals whose cases have been transferred into this MDL) filed another notice of supplemental authority (“Second Notice”), Doc. #: 2618. Distributors filed a response to West Boca’s second notice. Doc. #: 2681. West Boca filed a reply to Distributors’ response, again on behalf of all hospitals in the MDL. Doc. #: 2705. West Boca then filed a third notice of supplemental authority. Case No. 1:18-op-45530, Doc. #: 65.⁷

*2 The Court has reviewed all of the parties’ submissions. For the reasons stated below, the Court now rules as follows: Defendants’ Motions to Dismiss are GRANTED with respect to Count II (RICO § 1962(a)); Count V (Breach of Implied Warranty); Count VIII (Negligence Per Se); Count IX (Negligent Marketing); and Count X (Negligent Distribution). The motions are otherwise DENIED.

I. Legal Standard for a Motion to Dismiss

The principles governing review of a Motion to Dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) are well-settled, as this Court has previously articulated. See, e.g., *Report and Recommendation (“R&R”) on Motions to Dismiss Muscogee (Creek) Nation Claims*, Doc. #: 1499 at 2-3; *R&R on Motion to Dismiss Summit County Claims*, Doc. #: 1025 at 2-3. A court is “required to ‘accept all well-pleaded factual allegations of the complaint as true and construe the complaint in the light most favorable to the plaintiff.’” *Dinwiddie v. Beshear*, 2019 WL 4009835, at *2 (6th Cir. Apr. 24, 2019) (quoting *Dubay v. Wells*, 506 F.3d 422, 426 (6th Cir. 2007); see also *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009)).

Federal courts require only “notice pleadings” containing “a short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2). Accordingly, “a complaint need not contain ‘detailed

factual allegations,’ however, it requires more than ‘labels and conclusion’ or ‘a formulaic recitation of the elements of a cause of action.’” *Dinwiddie*, 2019 WL 4009835, at *2 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)). Rule 8 “demands more than an unadorned, the-defendant-harmed-me accusation,” and a complaint will not “suffice if it tenders ‘naked assertion[s]’ devoid of ‘further factual enhancement.’” *Iqbal*, 556 U.S. at 678, 129 S.Ct. 1937 (quoting *Twombly*, 550 U.S. at 557, 127 S.Ct. 1955).

A complaint will survive a motion to dismiss if it “contain[s] sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’”

Id. (quoting *Twombly*, 550 U.S. at 570, 127 S.Ct. 1955). Facial plausibility exists “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* (citing *Twombly*, 550 U.S. at 556, 127 S.Ct. 1955). Deciding if a complaint states a plausible claim for relief is “a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” *Id.* at 679, 129 S.Ct. 1937. A district court may dismiss a complaint for failure to state a claim “only if it’s clear that no relief could be granted under any set of facts that could be proved consistent with the allegations.” *Trollinger v. Tyson Foods, Inc.*, 370 F.3d 602, 615 (6th Cir. 2004) (quoting *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 514, 122 S.Ct. 992, 152 L.Ed.2d 1 (2002)); *Hishon v. King & Spalding*, 467 U.S. 69, 73, 104 S.Ct. 2229, 81 L.Ed.2d 59 (1984)).

II. Factual Allegations

In its Complaint, West Boca asserts the following claims:

- Count I, Violation Of RICO,⁸ 18 U.S.C. 1961, *et seq.* – Opioid False Narrative Enterprise (Against All Defendants);
- Count II, Violation Of RICO, 18 U.S.C. § 1962(a)&⁹ (d) (Against All Defendants);
- Count III, Violation Of Florida’s Deceptive And

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Unfair Trade Practices Act ([Fla. Stat. Ann. § 501.201, et seq.](#)) (Against All Defendants);

- Count IV, Fraudulent Practices – Misleading Advertising, Florida Statutes Title XLVI, Crimes § 817.41 (Against Marketing Defendants);⁹

*3 • Count V, Breach of Implied Warranty of Fitness For a Particular Purpose ([Fla. Stat. Ann. §§ 672.315](#) and 672.11, *et seq.*) (Against All Defendants);

- Count VI, Negligence (Against All Defendants);
- Count VII, Wanton Negligence (Against All Defendants);
- Count VIII, Negligence Per Se (Against All Defendants);
- Count IX, Negligent Marketing (Against Marketing Defendants);
- Count X, Negligent Distribution (Against All Defendants);
- Count XI, Nuisance (Against All Defendants); and
- Count XII, Unjust Enrichment (Against All Defendants). Many of the factual allegations that pertain to the Defendants' alleged behavior are the

same as those alleged in the complaints filed in the (i) *Summit County*, (ii) *Muscogee (Creek) Nation*, and (iii) *Blackfeet Tribe* cases.¹⁰ See Doc. #: 514; 731; 6.¹¹ The Magistrate Judge and this Court have addressed those factual allegations at length. See *Summit County R&R*, Doc. #: 1025; *Muscogee Nation R&R*, Doc. #: 1499; *Blackfeet Tribe R&R*, Doc. #: 1500; *Opinion and Order on Summit County*, Doc. #: 1203; *Opinion and Order on Tribe Cases*, Doc. #: 1680. Thus, the Court only provides below a brief overview of the factual allegations specific to West Boca, and incorporates by reference the general factual circumstances surrounding the opioid crisis and the allegations of Defendants' behavior that are common to the cases addressed in the aforementioned R&Rs and Orders.

A. Factual Allegations Against Defendants

*4 Plaintiff, West Boca Medical Center, is a 195-bed, acute-care hospital located in Palm Beach County,

Florida, which includes a pharmacy, emergency room (“ER”), and a 35-bed Neonatal Intensive Care Unit (“NICU”). West Boca also operates a separate ER facility in Broward County, Florida. Doc. #: 385 at ¶20.

West Boca alleges that the Manufacturer Defendants, also referred to as “Marketing Defendants,” manufacture, sell, and market prescription opioid painkillers and fueled the opioid crisis “through a massive marketing campaign premised on false and incomplete information,” which engineered a “dramatic shift in how and when opioids are prescribed by the medical community and used by patients.” Doc. #: 385 at ¶15. West Boca alleges the Marketing Defendants dramatically increased sales of prescription opioids despite their knowledge “that opioids were addictive and subject to abuse, and that their other claims regarding the risks, benefits, and superiority of opioids for long-term use were untrue and unfounded.” Doc. #: 385 at ¶16.

West Boca also alleges that the Distributor and Pharmacy Defendants, also referred to as “Supply Chain Defendants,” “participated in the conspiracy by ignoring their legal responsibilities under the Controlled Substance Act, and flooded affected areas with opioids well knowing they were contributing to, but profiting from, widespread addiction and human misery.” Doc. #: 385 at ¶17. West Boca further alleges that Marketing and Supply Chain Defendants “extract billions of dollars of revenue from the addicted American public while tens of millions of dollars of injury are caused to hospitals as the reasonably foreseeable consequences of the prescription opioid epidemic.” Doc. #: 385 at ¶19.

West Boca further alleges that hospitals in Southern Florida, where it is located, have been hit especially hard by the opioid crisis. West Boca alleges that, prior to 2009, Florida’s medical laws allowed physicians to prescribe and dispense opioids from their offices, with no prescription-monitoring system in place. Doc. #: 385 at ¶30. West Boca cites to statistics showing that “[b]y 2009, of the top oxycodone-prescribing counties in American, nine were in Florida...Broward County had four pain clinics in 2007 and 115 two years later.” Doc. #: 385 at ¶30. West Boca also provides statistics showing that “[i]n 2009, 25% of nationwide shipments of oxycodone were sent to the state of Florida. By 2010, 98 of the 100 doctors in the country who dispensed the highest quantities of oxycodone from their offices were located in Florida.” Doc. #: 385 at ¶31. West Boca further provides statistics regarding the costs of this epidemic, showing that in 2015, “health care costs related to opioid abuse in Florida

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reached \$1,246,526,068.00.” Doc. #: 385 at ¶38.

B. Facts Specific to Hospitals

In its Complaint, West Boca alleges that hospitals, such as itself, and especially those in south Florida, have been negatively impacted by the opioid crisis in at least three ways. First, West Boca alleges that hospitals must provide un- or under-compensated medical treatment to victims of the opioid crisis, at great expense to hospitals. Under various state and federal laws, hospitals are required to provide care to all patients who come in with any medical condition, including opioid addiction, regardless of whether the patient has the ability to pay for treatment. Further, it is often the case that patients who arrive at West Boca with opioid dependency issues will require extra or especially-complicated care compared with patients who do not have opioid-use issues. Exacerbating this situation, these “opioid patients” frequently do not have health insurance coverage or the ability to pay otherwise; and even when they do have insurance, hospitals are not compensated fully for the special care that may be required. See Doc. #: 385 at ¶¶53; 55; 57.

*5 Second, West Boca alleges that hospitals have been forced to incur additional operational costs associated with the opioid crisis. Because healthcare providers, such as those employed by West Boca, are themselves a potential source of opioid medication, hospitals frequently must utilize additional capital and human resources to identify and handle individuals who attempt to obtain opioids by deception—so-called “pill-seekers.” Hospital staffs require additional training and diagnostic tools to distinguish pill-seekers from legitimate patients, and hospitals need to hire additional personnel to help them keep their opioids secure. See Doc. #: 385 at ¶58.

Finally, West Boca alleges hospitals are also direct consumers of opioid pills. See Doc. #: 385 at ¶¶52; 62. Hospitals often run their own pharmacies, which purchase pills from distributors to be dispensed to hospital patients. Hospitals, of course, also have doctors and nurses on staff who were direct targets of the Defendants’ alleged misrepresentations. West Boca asserts these alleged misrepresentations caused their physicians to write more prescriptions than they otherwise would have, in turn causing them to have to purchase, stock, and fill more prescriptions for opioid medications than were warranted. See Doc. #: 385 at ¶52; 63.¹²

III. Causation under Florida Law

The Pharmacies assert that Florida’s “sole proximate cause” doctrine, and also the learned intermediary rule, each preclude a finding of proximate cause as a matter of law.¹³ See Doc. #: 686-1 at 2. They refer the Court to their briefing in *Broward County, Florida v. Purdue Pharma L.P., et al.*, Case No. 18-op-45332, MDL Doc. #: 582-1. As set forth below, the Court concludes neither of these doctrines compel dismissal of West Boca’s claims. As a general principle under Florida law, “[i]ssues of causation are problematic and, under most circumstances, should be left to the jury.”  *Simon v. Shearson Lehman Bros.*, 895 F.2d 1304, 1316 (11th Cir. 1990).

A. Sole Proximate Cause Doctrine

In their motion to dismiss Broward County’s claims, the Pharmacies assert that, “under Florida’s ‘sole proximate cause’ doctrine, the intentional misuse of a product such as a prescription opioid is, as a matter of law, the only legally relevant proximate cause of resulting injuries.” Doc. #: 582-1 at 3. The Pharmacies assert that “[a]ny injuries that [West Boca] might try to connect to the Moving Defendants’ conduct necessarily stem from the intentional misuse of diverted prescription opioids” and must, therefore, be dismissed. Doc. #: 582-1 at 3. Put simply, the Pharmacies assert the harms identified by West Boca were caused by the patients who consumed the opioid drugs. The Pharmacies cite three product liability cases to support this assertion:  *Labzda v. Purdue Pharma, L.P.*, 292 F. Supp. 2d 1346, 1356 (S.D. Fla. 2003);  *Bruner v. Anheuser-Busch, Inc.*, 153 F. Supp. 2d 1358, 1361 (S.D. Fla. 2001); and  *Clark v. Boeing Co.*, 395 So. 2d 1226, 1229 (Fla. Dist. Ct. App. 1981).

All three cases are distinguishable. The Florida Supreme Court has concluded that, under Florida law, a plaintiff’s knowing misuse of a product *does not* bar recovery, as a matter of law, on a products liability claim sounding in negligence, even if that misuse was done in an unforeseeable manner. *Standard Havens Prod., Inc. v.*

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Benitez, 648 So. 2d 1192, 1193 (Fla. 1994). Product misuse, under Florida law, is “a form of comparative negligence.” *Id.* at 1197. “Of course, if a court determines as a matter of law, or a jury determines as a matter of fact...that a claimant’s negligence was the *sole* legal cause of her injury, then, in such event, the claimant could not recover.” *Id.* (emphasis added).

*6 As a threshold matter, West Boca does not assert a products liability claim, so it is not clear that the sole proximate cause doctrine even applies in the present case.

Regardless, *Clark* is a Florida Appellate Court decision that was issued before *Standard Havens*, so to the extent the two cases conflict, *Standard Havens* is controlling.¹⁴ Similarly, *Bruner* and *Labzda* are cases decided by the Southern District of Florida; but the Supreme Court of Florida remains the ultimate arbiter of Florida law. See *Hortonville Joint Sch. Dist. No. 1 v. Hortonville Educ. Ass'n*, 426 U.S. 482, 488, 96 S.Ct. 2308, 49 L.Ed.2d 1 (1976) (“We are, of course, bound to accept the interpretation of [state] law by the highest court of the State.”). Thus, *Standard Havens* controls to the extent *Bruner* and *Labzda* conflict. In sum, *Standard Havens* trumps all three cases that defendants cite.

Moreover, the three cited cases are distinguishable and do not demand dismissal by their holdings. In *Clark*, the court clearly articulated the test for finding strict product liability: “The test is whether or not the product was reasonably safe for its intended use as manufactured and designed when it left the plant of the manufacturer.”

395 So. 2d at 1229. Here, West Boca has alleged that opioids are not reasonably safe for at least some of their advertised intended uses, and Defendants’ misrepresentations caused doctors to prescribe them for other than their safe uses. See Doc. #: 385 at ¶131 (“Defendants, however, have manufactured, promoted, marketed, and distributed opioids for the management of chronic pain by misleading consumers and medical providers.”). In *Labzda*, the court held that “foreseeable *voluntary* abuse of a non-defective product, such as alcohol, results in the legal conclusion that the proximate cause of the injury to the consumer was his *voluntary* abuse.”¹⁵ 292 F. Supp. 2d at 1356 (emphasis added). Similarly, in *Bruner*, the court concluded that, although there are dangers associated with the use of alcohol, “beer is not considered an ‘unreasonably dangerous’ product...because of the *common knowledge*

of these dangers.” 153 F. Supp. 2d at 1360–61 (emphasis added). Here, West Boca has alleged that the “abuse” by many patients was *not* voluntary because patients became addicted even when taking opioids as directed and prescribed by a doctor, and as advertised by Defendants; and both the doctors and patients were intentionally misled by Defendants about the dangers of opioids that were legally and “properly” prescribed for large doses over long periods of time. See, e.g., Doc. #: 385 at ¶131 (quoted above); ¶188. Accordingly, Florida’s sole proximate cause doctrine does not demand dismissal of West Boca’s claims.

B. Learned Intermediary Rule

*7 The Pharmacies also assert, in their motion to dismiss Broward County’s case, that a “doctor’s independent prescribing decision supersedes and breaks any causal link back to a distributor’s prior shipment of the medication to a pharmacy where the patient happened to fill it.” Doc. #: 582-1 at 4. The cases cited by the Pharmacies to support this assertion conclude that “[a] manufacturer of a dangerous commodity, such as a drug, does have a duty to warn but when the commodity is a prescription drug we hold that this duty to warn is fulfilled by an *adequate* warning given to those members of the medical community lawfully authorized to prescribe, dispense and administer prescription drugs.”

Buckner v. Allergan Pharm., Inc., 400 So. 2d 820, 822 (Fla. Dist. Ct. App. 1981) (citing *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974)) (emphasis added).

Again, the Defendants’ argument fails. First, the *Buckner* court’s analysis expressly turns on whether a drug manufacturer *adequately* warns a medical professional—precisely what West Boca alleges manufacturers did *not* do. Second, the same argument was expressly considered and rejected by Magistrate Judge Ruiz in the *Summit County Report and Recommendation*, and that analysis and conclusion remain applicable here. See Doc. #: 1025 at 29-30 (“the complaint alleges that prescribing physicians were also targets of the misrepresentations. Given these allegations, the court declines to find that the physicians’ act of writing prescriptions breaks the causal chain, as a matter of law, when the very purpose of the Defendants’ alleged scheme was to achieve exactly that result.”) This Court adopted

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this part of the *Summit County R&R*, see Doc. #: 1203.

The cases relied on by the Pharmacies do not purport to relieve a pharmacist—also a medical expert—from all responsibility stemming from the filling of prescriptions written by doctors. In fact, the court in *Buckner* expressly states that “Chapters 458, 465 and 500, Florida Statutes, evidences legislated public policy to rely on physicians **and pharmacists** to protect the consuming public from injury by product use when the product is a prescription drug.” *Buckner*, 400 So. 2d at 822 n.3 (citing Fla. Stat. Ann. (1979) at §§ 500.02(1) and 500.151 (repealed)) (emphasis added). Nowhere in its opinion does the *Buckner* court extend the learned intermediary rule under Florida law to pharmacies, which was the case under Oklahoma law in the *Muscogee* case. And even in *Muscogee*, this Court concluded that the Tribes’ claims against the Pharmacies, as both dispensers and distributors, would be allowed to proceed to fact discovery. See Doc. #: 1680 at 7-10. The same result is compelled here.

IV. RICO

West Boca’s allegations of RICO violations are similar to those alleged by other plaintiffs in this MDL. Specifically, West Boca alleges that all Defendants conducted and participated—through various acts of mail and wire fraud and violations of the Controlled Substances Act (“CSA”—in the conduct of a False Narrative Enterprise that created the opioid epidemic and injured West Boca, in violation of 18 U.S.C. § 1962(c). See Doc. #: 385 at ¶¶812-884. West Boca further alleges each Defendant derived income and invested the proceeds in an enterprise that injured West Boca, in violation of § 1962(a), and that each Defendant conspired with one another to do so in violation of § 1962(c). See Doc. #: 385 at ¶¶885-894.

Nothing in the parties’ briefs convinces the Court to revisit any of its prior analysis of the applicable RICO standard. See Doc. #: 1025; 1203. The question is whether and to what extent that standard should apply differently to a different type of plaintiff (a Hospital) alleging different types of injuries. In its previous orders,

the Court explained that the RICO statute should be liberally construed and should apply broadly in civil cases. See Doc. #: 1025 at 12 (citing *Boyle v. United States*, 556 U.S. 938, 944, 129 S.Ct. 2237, 173 L.Ed.2d 1265 (2009)); Doc. #: 1203 at 6 (citing *Sedima, SPRL v. Imrex Co., Inc.*, 473 U.S. 479, 498, 105 S.Ct. 3275, 87 L.Ed.2d 346 (1985)). The Court also explained that “RICO’s civil-suit provision imposes two distinct but overlapping limitations on claimants—standing and proximate cause.” *Trollinger v. Tyson Foods, Inc.*, 370 F.3d 602, 613 (6th Cir. 2004). RICO law has also been “interpreted to require that a private plaintiff show proximate cause in order to have standing to sue.” *Id.* at 612. Thus, as before, the Court will address the Defendants’ proximate cause arguments and then address their standing arguments; this time, however, the analysis involves claims by a Hospital, not a municipal entity, Indian Tribe, or third-party-payor.

A. Proximate Cause

*8 Under RICO, proximate cause consists of two distinct elements: foreseeability and directness. See *Perry v. Am. Tobacco Co.*, 324 F.3d 845, 850 (6th Cir. 2003) (citing *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 268-69, 112 S.Ct. 1311, 117 L.Ed.2d 532 (1992)) (“Though foreseeability is an element of the proximate cause analysis, it is distinct from the requirement of a direct injury.”). Directness, in the proximate cause context, requires **both** an analysis of the closeness of the relationship between the asserted injury and the alleged injurious conduct, **and** an evaluation of public policy considerations that reflect “ ‘ideas of what justice demands, or of what is administratively possible and convenient.’ ” *Holmes*, 503 U.S. at 268, 112 S.Ct. 1311 (quoting W. Keeton, D. Dobbs, R. Keeton, & D. Owen, *Prosser and Keeton on Law of Torts* § 41, p. 264 (5th ed. 1984)).

As stated previously, the alleged injurious conduct of these Defendants is substantially similar to that which was alleged by Summit and Cuyahoga Counties in Track One, the first Opiate MDL bellwether trial. West Boca’s asserted injuries, however, are different. Where Summit County alleged thirteen categories of injuries,¹⁶ West Boca asserts only three:

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1. Unreimbursed charges for treatment of patients with opioid conditions. Doc. #: 385 at ¶55.
2. Increased operational costs for: (a) providing more and more-complicated care to opioid addicts, and (b) dealing with “pill seekers.” Doc. #: 385 at ¶55-58.
3. Increased costs as a purchaser of opiates from Defendants. Doc. #: 385 at ¶¶62-63.

The Court concludes that West Boca has presented sufficient factual allegations that at least some of their asserted injuries are a foreseeable result of the Defendants’ purported failures that allegedly created the opioid crisis. However, even when a causal connection is foreseeable, it is well-settled that a disconnected and efficient intervening cause may break the causal chain.

See  *Johnson v. Kosmos Portland Cement Co.*, 64 F.2d 193, 195 (6th Cir. 1933); see also   *Tardif v. P.E.T.A.*, 829 F. Supp. 2d 1219, 1234 (M.D. Fla. 2011) (“[A] Defendant is not liable when a separate force or action is the active and efficient intervening cause, the sole proximate cause or an independent cause of the plaintiff’s damages.”). On the other hand, “when an intervening cause is foreseeable to the defendant, he may still be held liable.”   *Tardif*, 829 F. Supp. 2d at 1234.

The Manufacturer Defendants attempt to rely on the fact that West Boca is legally obligated to treat patients to conclude that, but for this purported intervening obligation, West Boca might not have been damaged at all. They assert that “applicable federal and state law defeats causation because any alleged harm to West Boca stems from these legislative public-policy decisions.” Doc. #: 691-1 at 5. Thus, according to the Manufacturers, an intervening legislative public-policy decision breaks the causal chain. The Manufacturers cite no case law to support this assertion. West Boca, on the other hand, asserts that its legal obligation to treat patients actually makes it *more* foreseeable that it would be harmed by the opioid crisis. See Doc. #: 806 at 17-18. The Court finds West Boca’s argument more persuasive. The Emergency Medical Treatment and Labor Act (“EMTALA”), 42 U.S.C. § 1395dd, was enacted by congress in 1986 and requires hospitals to provide, at a minimum, medical screening and stabilization of every patient’s medical condition prior to transfer. Doc. #: 385 at ¶41. EMTALA and related state statutes requiring hospitals to treat all patients make West Boca’s injuries, if anything, a more foreseeable consequence of the Defendants’ actions

related to the opioid crisis. Thus, the Court concludes at least some of West Boca’s asserted injuries are a foreseeable result of Defendants’ alleged conduct.¹⁷

*9 That the creation of an opioid crisis foreseeably led to increased costs for hospitals, however, does not end the inquiry. Under RICO law, the injury must also be a direct consequence of a Defendant’s injurious conduct. No Defendant meaningfully develops any argument that either the second or third categories of West Boca’s alleged damages are too tenuous to support proximate cause. The Defendants’ arguments for dismissal of West Boca’s RICO claims only address the first category of damages – the cost of unreimbursed medical treatment.¹⁸

Regarding this first category of damages, closer scrutiny under  *Holmes* is warranted. Some of the Defendants’ arguments regarding the first category of damages are persuasive, and the Court has some reservations about the viability of this category of claimed damages under the applicable RICO standard.¹⁹

Defendants rely primarily on two cases, in which hospitals brought claims seeking damages for unreimbursed medical expenses related to tobacco use:  *Association of Washington Pub. Hosp. Districts v. Philip Morris Inc.*, 241 F.3d 696, 702 (9th Cir. 2001), and  *Allegheny Gen. Hosp. v. Philip Morris, Inc.*, 228 F.3d 429, 435 (3d Cir. 2000). In both cases, the plaintiffs’ claims were dismissed. However, the circuit courts analogized the plaintiffs’ claims to the claims of third-party payors. After carefully reviewing and comparing the complaints of West Boca and Cleveland Bakers, Doc. #: 3031, the Court is not convinced that the claims are, in fact, similar. Thus, the third-party payor cases cited by West Boca and the Defendants may be of limited value.²⁰

*10 The factual and legal distinctions between third-party payors and hospitals are manifest. As a general matter, when West Boca provides care to a patient, West Boca becomes a creditor to that patient, who in turn owes a debt to West Boca for services rendered. It is not uncommon, therefore, for hospitals to sell patient debt to a collection agency or to bring a creditor lawsuit against the patient. It is, thus, also not surprising that courts have found medical debt is consumer debt under various statutes. See, e.g.,  *Baisden v. Credit Adjustments, Inc.*, 813 F.3d 338 (6th Cir. 2016) (Telephone Consumer Protection Act (“TCPA”));  *Mais v. Gulf Coast Collection Bureau*,

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Inc., 768 F.3d 1110 (11th Cir. 2014) (Fair Debt Collection Practices Act (“FDCPA”)).

This creditor-debtor relationship is factually distinct from the legal relationship that exists between a third-party payor and its members. While a hospital provides a service and then seeks compensation from the patient (regardless of whether the patient has a right to recover from a third-party tortfeasor or not), a third-party payor generally has a subrogation right to recover medical expenses from a third-party tortfeasor on its member’s behalf. A hospital, so far as the Court is aware, has no analogous right; and West Boca does not argue that it does.²¹ On this point, Defendants assert there is long-standing, common-law precedent that hospitals *do not* have a direct cause of action in tort against a tortfeasor who allegedly injures the patient, even if it imposes increased costs on the hospital. Doc. #: 684-1 at 4 (citing  *United Food & Commercial Workers Unions, Employers Health & Welfare Fund v. Philip Morris, Inc.*, 223 F.3d 1271, 1274 (11th Cir. 2000)). Thus, it appears that, while a third-party payor may pursue a claim against a third-party tortfeasor who injures a patient-insured, a hospital’s only claim is against the patient. Unfortunately, this distinction is not briefed by the parties or carefully drawn in the tobacco cases cited by Defendants.²²

At least with respect to unreimbursed charges for medical treatment, this distinction places West Boca’s injury at least one step further removed from the injurious conduct of the Defendants. The  *Holmes* factors are thus implicated regarding the first category of West Boca’s alleged damages in a way that West Boca’s other alleged categories of injuries are not. In  *Holmes*, the Supreme Court articulated three policy concerns that arise when an injury is not a sufficiently direct result of a defendants’ conduct:

*11 First, the less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff’s damages attributable to the violation, as distinct from other, independent, factors. Second, quite apart from problems of proving factual causation, recognizing claims of the indirectly injured would force courts to adopt

complicated rules apportioning damages among plaintiffs removed at different levels of injury from the violative acts, to obviate the risk of multiple recoveries. And, finally, the need to grapple with these problems is simply unjustified by the general interest in deterring injurious conduct, since directly injured victims can generally be counted on to vindicate the law as private attorneys general, without any of the problems attendant upon suits by plaintiffs injured more remotely.

 *Holmes*, 503 U.S. at 269–70, 112 S.Ct. 1311 (internal citations omitted).

The first  *Holmes* factor is applicable to the present analysis.²³ West Boca alleges its unreimbursed costs have increased due to an increase in both: (1) hospitalizations for opioid-related injuries (e.g. overdoses) and (2) the cost of providing care for “normal” conditions exacerbated by opioid use (e.g. child-birth). West Boca asserts that instances like the latter are made more complicated and expensive when the patient has an opioid use disorder. While it is likely relatively easy to ascertain damages in the former situation—that the care provided for an opioid overdose is easily attributable to the opioid crisis—the latter situation is more complicated.

Child birth presents a good illustration of the potential difficulty. If a woman is considered a high-risk pregnancy due to advanced age or a preexisting medical condition, but is also addicted to opioids, it is not clear to the Court how it will be possible to distinguish what portion of West Boca’s increased costs for those pregnancy services will be attributable to one complicating factor over any other. Nevertheless, such apportionment is rightfully the subject of expert discovery, and the Court will allow that discovery to occur.

Despite these reservations, the situation in this case is not that meaningfully different from *Summit County* and *Cleveland Bakers*. In those cases, the Court also expressed its reservations about the viability of certain categories of damages. In each case, however, where the plaintiff had alleged at least one category of damages that

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set forth a plausible claim for relief, the Court declined to dismiss the entire claim. See Doc. #: 1203 at 15-16; Doc. #: 3177 at 35-36. The same conclusion is equally appropriate here. Therefore, the Court concludes West Boca has sufficiently alleged at least one plausibly direct and foreseeable chain of causation from injurious conduct to alleged injury to survive a motion to dismiss for lack of proximate cause.

B. Standing

Having determined that West Boca's injuries are not too far removed from Defendants' conduct, the Court turns to the standing analysis—that is, whether hospitals are the appropriate plaintiffs to bring these claims. As the Court has previously articulated:

Title 18 of the U.S. Code, section 1964(c), has been deemed the standing provision of RICO. It provides that “[a]ny person injured in his business or property by reason of a violation of section 1962 of this chapter may sue therefor ...and shall recover threefold the damages he sustains and the cost of the suit, including reasonable attorney’s fee.” 18 U.S.C. § 1964(c). The two operative portions of this section are the “business or property” limitation and the “by reason of” limitation.

“The ‘by reason of’ limitation...bundles together a variety of ‘judicial tools,’ some of which are traditionally employed to decide causation questions and some of which are employed to decide standing questions.” *Trollinger*, 370 F.3d at 613 (citing *Holmes*, 503 U.S. at 268, 112 S.Ct. 1311.). As it pertains to standing, the “by reason of” limitation is used to analyze whether a plaintiff is asserting an injury that was borne directly by that plaintiff or whether the injury was “derivative or passed- on” to the plaintiff by some intermediate party. See *id.* at 614.

*12

* * *

Even if Plaintiffs' asserted injuries were proximately and directly caused “by reason of” Defendants' alleged injurious conduct, Plaintiffs still may not bring a RICO claim if the injuries asserted were not to their “business or property.” 18 U.S.C. § 1964(c). As a general

principal, “money, of course, is a form of property.”

Reiter v. Sonotone Corp., 442 U.S. 330, 338, 99 S.Ct. 2326, 60 L.Ed.2d 931 (1979). It is also true that, “[a] person whose property is diminished by a payment of money wrongfully induced is injured in his property.” *County of Oakland v. City of Detroit*, 866 F.2d 839, 845 (6th Cir. 1989) (quoting *Chattanooga Foundry and Pipe Works v. City of Atlanta*, 203 U.S. 390, 396, 27 S.Ct. 65, 51 L.Ed. 241 (1906)).

Doc. #: 1203 at 10-11; 12-13.

Defendants rely heavily on *Jackson v. Sedgwick Claims Mgmt. Services*, 731 F.3d 556 (6th Cir. 2013), to argue that West Boca has not alleged any injury to any business or property, but has instead only alleged injuries that flow from the personal injuries of its patients. See Doc. #: 684-1 at 9; 691-1 at 2. However, as articulated in its *Summit County* Opinion, the Court believes *Jackson* is factually distinct from these opioid cases generally, and also disagrees with Defendants' characterization of the law as set forth by the Sixth Circuit in *Jackson*. Doc. #: 1203 at 13. It is true that *Jackson* stands for the proposition that “personal injuries and pecuniary losses flowing from those personal injuries fail to confer relief under § 1964(c).” *Jackson* at 565-66,. However, after carefully reviewing the facts of *Jackson* and the several cases cited therein, the Court concluded that a pecuniary loss “flows from” a personal injury “when the alleged RICO injury merely acts as an alternate theory for recovering damages otherwise available in a tort claim for personal injury and is asserted by the plaintiff him- or herself.” Doc. #: 1203 at 14.

Here, West Boca is in the business of providing a service. Its asserted injuries stem from (1) not being adequately compensated for the services provided, (2) the increased operational costs of providing those services, and (3) the increased cost of purchasing supplies necessary for the provision of those services, respectively. These categories of injuries are injuries to business or property. That West Boca is in the business of providing **healthcare** services, does not make its injuries “derivative” of personal injuries, because “[i]f any claim merely derivative of a personal injury barred RICO liability, then...doctors, hospitals, and any number of nonprofits directly injured in their business dealings *involving* personal injuries would

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as well. This is not how the Court interprets the holding in *Jackson*.” *State Farm Mut. Auto. Ins. Co. v. Universal Health Grp., Inc.*, No. 14-CV-10266, 2014 WL 5427170, at *8 (E.D. Mich. Oct. 24, 2014) (emphasis added).

Furthermore, operational costs such as “capital improvement costs,” “additional security costs,” and “additional training and educational costs for hospital personnel,” Doc. #: 806 at 34-35. (citing Doc. #: 385 at ¶¶51-58), as well as costs associated with being falsely induced to purchase and prescribe more opioid pills than were appropriate, are direct costs to hospitals that allegedly were borne as a result of the opioid crisis itself, not simply as a result of treating injured patients. Doc. #: 806 at 7-8. As alleged, these are classic business costs.

*13 Again, however, the Court must draw what it views as an important distinction between unreimbursed medical expenses and the other two asserted categories of injury. In the case of unpaid medical bills, it is not entirely clear that the medical expenses injury does not belong, in whole or in part, to the patients. That is, in terms of RICO law, it is not immediately apparent that West Boca’s alleged injury from the provision of unreimbursed medical services was caused “by reason of” a substantive RICO violation, or instead that this particular category of injury was “passed-on” by the injured patients (specifically those patients’ inability to pay for the services rendered).

As stated in the proximate cause section above, the Defendants maintain that a hospital does not have a direct cause of action in tort against a tortfeasor who allegedly injures the patient. Doc. #: 684-1 at 4 (citing *United Food*, 223 F.3d at 1274). The Third Circuit in *Allegheny Gen. Hosp.* articulated the slippery slope that forms the policy rationale behind this argument. See *Allegheny Gen. Hosp.*, 228 F.3d at 445 (“The Hospitals are dangerously close to asserting that they have standing to sue any company that causes a nonpaying patient’s disease or illness.”). As a general matter, the Court is concerned, as was the Third Circuit, about the precedent of allowing healthcare providers to recover the increased costs of providing care to their allegedly wrongfully-injured patients. While the opioid crisis is inarguably unlike any mass tort this country has ever faced, the Court is skeptical that it should attempt to engage in the type of line-drawing necessary to determine what type of crises a defendant would need to create in

order to give hospitals standing to sue that defendant for the unreimbursed costs of treating such a crisis, especially where individual plaintiffs are also attempting to vindicate their own rights.

In this MDL alone, there are scores of cases brought by individual parties seeking compensation for various damages, including their medical bills. If hospitals are damaged by patients not paying their medical bills, their remedy—as discussed above—should be to seek compensation from the patients who are not paying those bills. To the extent the Defendants are liable to the patients for the costs of medical bills, it ought to be the patients’ responsibility to hold the Defendants liable as “private attorneys general.”²⁴ See *Holmes*, 503 U.S. at 269-70, 112 S.Ct. 1311. The Court is concerned it might be forced to establish a complicated remedial scheme to adequately apportion damages between patients and hospitals, so that Defendants will not be subject to duplicative recoveries from each. This is the exact problem about which the second and third *Holmes* factors caution, see *id.*, and, as Defendants point out, something courts in the tobacco cases nearly unanimously declined to do.

Nevertheless, West Boca asserts that reliance on prior tobacco cases as precedent for the opioid crisis is misplaced and articulates nine paragraphs of factual distinctions between their opioid case and the tobacco cases. See Doc. #: 806 at 19-21. While the Court is hesitant to find that hospitals have standing to bring a RICO claim for their unreimbursed medical expenses, the Court will allow the RICO claim with respect to this injury to proceed for two reasons. First, in the municipality cases, the Tribe cases, and the third-party payor case, the Court concluded it would not (*at the motion to dismiss stage*) draw distinctions between the various alleged categories of injuries. Such distinctions regarding damages are better drawn after discovery has fleshed out the factual record. Second, as West Boca carefully points out, there are a large number of factual distinctions between opioid cases and tobacco cases generally, and some of those factual distinctions may reasonably require further development. Thus, because the RICO claim is plausible on at least one theory of damages and because West Boca raises significant factual issues not suitable for resolution on a motion to dismiss, discovery will proceed as to the entire claim.

*14 As a final thought, neither the tobacco cases cited by the parties, nor the parties’ briefs, adequately draw any

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meaningful distinctions between hospitals' asserted injuries and those of third-party payors. The parties should have an opportunity to address the factual distinctions between hospitals, third-party payors, and municipalities with respect to the injuries alleged and with respect to the legal standard articulated by the Court. Thus, the Court concludes that West Boca has standing to bring its RICO claims against these Defendants.

C. Other RICO Arguments

1. Previously Addressed RICO Arguments

Defendants make several arguments that the Court has addressed in prior orders. The Defendants assert that reporting-based violations of the CSA cannot constitute predicate acts under RICO;²⁵ that West Boca did not adequately plead the existence of a RICO enterprise;²⁶ and that West Boca failed to adequately plead an agreement sufficient to support a RICO conspiracy claim under § 1962(d).²⁷ The Defendants also argue that West Boca's allegations of mail and wire fraud do not meet the heightened pleading requirements under Rule 9(b) of the Federal Rules of Civil Procedures, and constitutes impermissible "group pleading."²⁸

The Court has addressed the merits of each of these arguments before. See Doc. #: 1025 at 36-39 (existence of an enterprise), 39-48 (predicate acts), 39-42 (Rule 9(b)), 37-44 (conspiracy generally), 97-98 (conspiratorial agreement);²⁹ Doc. #: 1680 at 2-4 (Rule 9(b)), 4-5 (group pleading); see also Opinion and Order Regarding Conspiracy claims, Doc. #: 2562 (setting out an analysis of the alleged agreement between many of the same Defendants on substantially similar factual allegations); Opinion and Order Regarding RICO claims, Doc. #: 2580 at 2-3 (CSA violations as predicate acts), 3-6 (existence of an enterprise); Evidentiary Order Regarding Track One Pretrial Motions, Doc. #: 3058 at 24 (CSA violations as predicate acts).

Upon careful review of the parties' briefs, the Court concludes its prior analyses apply with equal force to the facts alleged in West Boca's complaint. Accordingly, the Court incorporates its legal analyses from the aforementioned orders and rejects the Defendants' contentions that dismissal is mandated in this action by

inadequate pleading of (1) the existence of an enterprise, (2) predicate acts, (3) conspiratorial agreement,³⁰ or (4) Fed. R. Civ. P. 9(b)'s particularity requirement.

2. Pharmacy Liability Under RICO

*15 The Pharmacy Defendants assert that:

[i]f anything, Plaintiff's RICO claims against [the Pharmacies] are even more implausible than RICO claims against the other defendants. Whatever the other bellwether plaintiffs may have believed to be the merits of a RICO claim against the manufacturer or major distributor defendants, they have uniformly recognized that no such claim is feasible against the Moving Defendants. Alone among the bellwether plaintiffs, Plaintiff here asserts RICO claims against the Moving Defendants as well.

Doc. #: 686-1 at 3. The Pharmacies' argument appears to be that, since no other plaintiffs alleged RICO claims against them, West Boca's claims against them should be dismissed. This is, of course, not the legal standard for a motion to dismiss. The Court is not persuaded by what claims may or may not have been filed by other types of plaintiffs in other cases (e.g., municipal entities or Tribes), but instead must look at the plausibility of what the Plaintiff in this case actually alleged in its complaint.

The Pharmacy Defendants also assert, conclusorily, that "to whatever extent Plaintiff intended to assert claims against the Moving Defendants as pharmacies rather than as distributors, its pleading does not pass muster under *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009)." Doc. #: 686-1 at 2. This assertion is plainly inaccurate.³¹

In its response, West Boca asserts that the Pharmacy Defendants "participated in the False Narrative

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conspiracy through their intentional acts designed (among other things) to conceal conspicuous anomalies in the distribution patterns of opioids, and reaped tremendous profits in the process.” Doc. #: 806 at 22-23; (citing Doc. #: 385 at ¶¶870 (alleging a common purpose); 509-514, 519-569 (alleging breach of duty to prevent diversion by Distributors); 663-707 (alleging breach of duty to prevent diversion by National Retail Pharmacies). These allegations are sufficient to state plausible claims against and provide notice to the Pharmacies as distributors and dispensers of opioids generally, and also with respect to West Boca’s RICO claim as described above.

D. Investment Injury Under 18 U.S.C. § 1962(a)

Defendants assert that West Boca’s Section 1962(a) claim fails because West Boca does not allege an injury specifically caused by any of the Defendants’ investment of income obtained through racketeering activity. See Doc. #: 684-1 at 12-13; Doc. #: 961-1 at 67. For the reasons that follow, the Court agrees.

Section 1962(a) of RICO provides in relevant part:

It shall be unlawful for any person who has received any income derived, directly or indirectly, from a pattern of racketeering activity...to use or invest, directly or indirectly, any part of such income, in acquisition of any interest in, or the establishment or operation of, any enterprise which is engaged in, or the activities of which affect, interstate or foreign commerce.

*16 18 U.S.C. § 1962(a).

A majority of Circuits, including the Sixth, have concluded that, “in order to state a claim under § 1962(a), a plaintiff must plead a specific injury to the plaintiff caused by the investment of income into the racketeering enterprise, distinct from any injuries caused by the predicate acts of racketeering.” *Vemco, Inc. v.*

Camardella, 23 F.3d 129, 132 (6th Cir. 1994) (citing *Craighead v. E.F. Hutton & Co., Inc.*, 899 F.2d 485, 494 (6th Cir.1990)); see also *Beck v. Prupis*, 529 U.S. 494, 506 n.9, 120 S.Ct. 1608, 146 L.Ed.2d 561 (2000) (while expressing no view on the issue, noting that “most courts of appeals have adopted the so-called investment injury rule, which requires that a plaintiff suing for a violation of § 1962(a) allege injury from the defendant’s ‘use or invest[ment]’ of income derived from racketeering activity”) (citing *Vemco*, 23 F.3d at 132).

When an enterprise receives the proceeds of its racketeering activity against a plaintiff, and then merely reinvests the proceeds of its racketeering activity in itself so that it can continue to operate (and presumably further injure the plaintiff via continued racketeering activity), such investment does not give rise to a § 1962(a) claim under the majority rule. This is because,

[o]ver the long term, corporations generally reinvest their profits, regardless of the source. Consequently, almost every racketeering act by a corporation will have some connection to the proceeds of a previous act.

Section 1962(c) is the proper avenue to redress injuries caused by the racketeering acts themselves. If plaintiffs’ reinvestment injury concept were accepted, almost every pattern of racketeering activity by a corporation would be actionable under § 1962(a), and the distinction between § 1962(a) and § 1962(c) would become meaningless.

Brittingham v. Mobil Corp., 943 F.2d 297, 305 (3d Cir. 1991), overruled on other grounds by *Jaguar Cars, Inc. v. Royal Oaks Motor Car Co.*, 46 F.3d 258 (3d Cir. 1995). Thus, under the majority rule, a plaintiff may have standing under § 1962(a) in one of two ways. A plaintiff can allege that a defendant either: (1) used or

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invested its ill-gotten racketeering income in a separate enterprise that injured the plaintiff,³² or (2) used for itself or invested in itself ill-gotten racketeering income from prior separate racketeering activity, thus allowing it to injure the plaintiff.³³

*17 The question at issue here, then, is whether any of West Boca's asserted injuries stem from some investment of the Defendants allegedly ill-gotten income. The Court concludes that, as alleged in West Boca's Complaint, they do not. West Boca expressly alleges that "Defendants, having income derived, directly or indirectly, from a pattern of racketeering, in which it participated as a principal within the meaning of 18 U.S.C. § 2, **used or invested, directly or indirectly, part of such income in itself**, an enterprise." and that West Boca "was injured...through the above-referenced acts of racketeering" Doc. #: 385 at ¶¶892; 894 (emphasis added). Thus, West Boca expressly asserts that the Defendants merely reinvested their allegedly ill-gotten racketeering income in themselves as enterprises and used that reinvestment to further propagate their alleged pattern of racketeering activity (false marketing and failure to prevent diversion). Under controlling Sixth Circuit precedent, these allegations are insufficient to confer standing on West Boca to assert a § 1962(a) claim. West Boca's Second Claim for Relief must be dismissed.³⁴

V. Nuisance

West Boca alleges the opioid epidemic is a public nuisance. Doc. #: 385 at ¶153. Specifically, West Boca asserts "[t]he nuisance is the over-saturation of opioids in the patient population of [West Boca] and in the geographic area served by [West Boca]..., as well as the adverse social, economic, and human health outcomes associated with widespread illegal opioid use." Doc. #: 385 at ¶991. West Boca alleges that Defendants "substantially participated in nuisance-causing activities" through facilitating the sale of prescription opioids and failing to maintain effective controls to prevent diversion to the general public. Doc. #: 385 at ¶¶992-994.

As with RICO, many of Defendants' arguments for dismissal were raised and ruled upon in other actions in this MDL. Although most of those actions, *Summit*

County, Muscogee (Creek) Nation, and Blackfeet Tribe, involve governmental entities, at least one action, *Cleveland Bakers*, was brought by a private plaintiff. Florida, like Ohio, follows the Restatement (Second) of Torts, so in order for West Boca to have standing to assert a public nuisance claim, it must assert a "special or peculiar injury to an individual different in kind and not merely in degree from the injury to the public at large."

Brown v. Fla. Chautauqua Ass'n, 59 Fla. 447, 451, 52 So. 802 (1910); see also *Fla. Wildlife Fed'n v. State Dep't of Envtl. Regulation*, 390 So. 2d 64, 67 (Fla. 1980).

Defendants assert West Boca has not alleged any injury that is different from that suffered by the general public. In addition, Defendants also assert: (1) they lacked control over the instrumentality of the nuisance; (2) West Boca's injuries are not connected to the use and enjoyment of property; and (3) West Boca has not alleged an interference with a public right. Finally, Defendants assert their actions are protected by a Florida "Safe Harbor" law.³⁵ The Court addresses each assertion below.

First, Defendants assert "West Boca's injuries are merely derivative, and, for that reason, they are not different or special, but the same as the alleged 'public' injury." Doc. #: 684-1 at 15. As described in Section IV.B. above, however—at least with respect to increased operational costs and direct purchase of excess opioid pills—West Boca has alleged concrete economic costs, unique to hospital entities, that are different than the alleged interference with human health outcomes suffered by the general public as a result of the opioid crisis. Therefore, as in *Cleveland Bakers*, and subject to the Court's prior analysis that the unreimbursed costs of medical care may not be West Boca's injury to assert, the Court concludes that "Plaintiffs have plausibly pled they sustained concrete economic losses differing in kind from the generalized injury to public health, safety, and wellness suffered by the general public as a consequence of the multi-faceted opioid crisis." Doc. #: 3177 at 43.

*18 Next, with respect to Defendants' arguments regarding control over the instrumentality of the nuisance and interference with a public right, the Court has carefully addressed each of these arguments in prior orders and nothing in the parties' briefs here convinces the Court to revisit that analysis. See, e.g., Doc. #: 1680 at 19 (concluding that "Defendants had control over the instrumentality of the nuisance by virtue of their control over their own opioid marketing, distribution, or dispensing practices.") (adopting Doc. #: 1499 at 57; Doc.

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#: 1500 at 31); Doc. #: 1680 at 18-19 (reviewing the Restatement (Second) of Torts § 821B and concluding that “ ‘public health’ has traditionally been considered a ‘public right.’ ”) (adopting Doc. #: 1499 at 59-61 and Doc. #: 1500 at 28-30); *see also* Doc. #: 3177 at 45 (same).

Distributor Defendants also assert that nuisance law in Florida requires an interference with the use and enjoyment of property. In support of this conclusion, Distributors cite an unreported Florida circuit court decision concluding that “[p]ublic nuisance does not apply to the design, manufacture, and distribution of a lawful product.” Doc. #: 591-1 at 9 (citing  *Penelas v. Arms Tech., Inc.*, No. 99-1941 CA-06, 1999 WL 1204353, at *4 (Fla. Cir. Ct. Dec. 13, 1999), aff’d, 778 So. 2d 1042 (Fla. Dist. Ct. App. 2001)). Even if the Court found this Florida trial court decision persuasive (much less precedential), the case still does not require a nuisance claim to allege interference with the use and enjoyment of land.

In response to this argument, West Boca refers the Court to *Estep v. State ex rel. Caro*, where the Florida Supreme Court concluded that “the practice of medicine by one without a license and also without learning and skill in treating the sick is a nuisance *per se*.³⁶ 156 Fla. 433, 434, 23 So.2d 482 (1945). While also not directly on point, this opinion from the state’s highest court suggests that Florida allows for at least some non-property-related nuisance claims. As dictated by the Court’s prior application of the *Erie* doctrine to nuisance law, West Boca’s argument is better taken. *See* Doc. #: 1680 at 11-13; 16-17 (adopting and expanding on the analysis from Doc. ##: 1499; 1500). The Court concludes that Florida nuisance law does not require an interference with the use and enjoyment of property.

Finally, regarding Florida’s “safe harbor,” the parties implicitly agree that, to whatever extent Florida law incorporates a safe harbor provision for the manufacture, distribution, or sale of lawful products, the Court’s prior analysis under Ohio law is controlling. *See* Doc. ##: 684-1 at 14-17; 686-1 at 4;³⁷ 691-1 at 15-17; 806 at 31-39 (each Party expressly incorporating *Summit County* briefs by reference). The Court has previously concluded under Ohio and Montana law that “ ‘safe harbor’ immunity from absolute nuisance liability is available only to those who perform in accord with their applicable licensing regulatory obligations. The Complaint alleges Defendants did not comply with the regulatory scheme, but rather

violated it.” Doc. #: 3177 at 47. The Court concluded in those cases, as it does here, that West Boca’s complaint sufficiently pleads conduct that is incompatible with defendants’ statutory authority and that the nuisance claim is therefore viable.³⁸ *See* Doc. #: 3177 at 46-47 (citing Doc. #: 1680 at 17-18, concurring with the analysis of Doc. #: 1500 at 26-28). Accordingly, the Court concludes West Boca has sufficiently alleged an actionable public nuisance claim.

VI. Florida’s Deceptive and Unfair Trade Practices Act

A. Plaintiff’s FDUTPA Claims Against All Defendants

*19 West Boca’s Third Claim for Relief alleges each Defendant engaged in “unfair or deceptive acts or practices” in violation of Florida’s Deceptive and Unfair Trade Practices Act (“FDUTPA”), *Fla. Stat. Ann. § 501.201, et seq.* (2007). Doc. #: 385 at ¶¶895-913. Specifically, West Boca alleges:

[e]ach of the Defendants have engaged in unfair and/or deceptive trade practices by omitting the material fact of its failure to design and operate a system to disclose suspicious orders of controlled substances (“SOMS”), as well as by failing to actually disclose such suspicious orders, as required of ‘registrants’ by the federal CSA,  21 C.F.R. § 1301.74(b), which is incorporated into Florida law by the FLDCA [Drug and Cosmetic Act], including  Fla. Stat. § 499.0121.

Doc. #: 385 at ¶902. West Boca further asserts that Defendants’ violations of the FDUTPA “offend Florida’s public policy, are immoral, unethical, oppressive and unscrupulous, as well as malicious, wanton and

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manifesting of ill will,” thereby causing substantial injury to West Boca, and that “[b]y reason of their reliance on Defendants’ misrepresentations and omissions of material fact, Plaintiff, physicians, patients, and/or others suffered actual pecuniary damage.” Doc. #: 385 at ¶903; ¶911.

Finally, West Boca alleges “the Marketing Defendants have each engaged in unfair and deceptive acts or practices in commerce in violation of the FDUTPA by actively promoting and marketing the use of opioids for indications not federally approved, circulating false and misleading information concerning opioids’ safety and efficacy, and downplaying or omitting the risk of addiction arising from their use.” Doc. #: 385 at ¶901.

B. FDUTPA Legal Standards

The FDUTPA is Florida’s consumer-protection law. It is intended to “protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce.” Fla. Stat. §§ 501.202(2) and § 501.204. A successful claim for damages under FDUTPA contains three elements: (1) a deceptive act or unfair practice in the course of trade or commerce; (2) causation; and (3) actual damages. See *Carriuolo v. Gen. Motors Co.*, 823 F.3d 977, 983-84 (11th Cir. 2016). The Florida legislature specifically provided that the FDUTPA “shall be construed liberally.” Fla. Stat. § 501.202(2); see also *State Farm Mut. Auto. Ins. Co. v. Performance Orthopaedics & Neurosurgery, LLC*, 315 F.Supp.3d 1291, 1307 (S.D. Fla. 2018) (“when considering whether a defendant’s actions support a finding of ‘unfair methods of competition, unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce,’ courts have regarded the concept as ‘extremely broad’ ”).

C. FDUTPA Analysis

1. Pleading Requirements

Defendants assert West Boca’s FDUTPA claim should be dismissed because West Boca has not pled sufficient

factual allegations to support the claim. Distributors and Pharmacies assert West Boca’s FDUTPA claim must meet the heightened pleading requirements under Rule 9(b) of the Federal Rules.³⁹ See Doc. #: 684-1 at 23-25; Doc. #: 686-1 at 5. Courts in Florida are split on whether Rule 9(b) applies to FDUTPA claims. See *State Farm*, 278 F.Supp.3d at 1327-28 (S.D. Fla. 2017) (comparing cases finding that Rule 9(b) does not apply to FDUTPA claims with cases finding it does); see also *Weiss v. General Motors LLC*, 418 F.Supp.3d 1173 (S.D. Fla. 2019) (following prior court decisions and holding that the requirements of Rule 9(b) do not apply to a claim under FDUTPA “[b]ecause ‘FDUTPA claims seek a remedy for conduct distinct from traditional common law torts such as fraud[,]’ ”) (citing *Harris v. Nordyne, LLC*, No. 14-cv-21884, 2014 WL 12516067, at *4 (S.D. Fla. Nov. 13, 2014)).

*20 The Court need not analyze whether Rule 9(b) applies to West Boca’s FDUTPA claims, however, because in any event the allegations within the Complaint are “sufficiently detailed to meet the requirements of Rule 9(b).” *Marty v. Anheuser-Busch Cos., LLC*, 43 F.Supp.3d 1333, 1338 (S.D. Fla. 2014). The Court has addressed similar Rule 9 arguments in its prior opinions and the same analysis applies to the allegations—and the sufficiency thereof—in West Boca’s Complaint. See, e.g., Doc. #: 1680 at 2-4 (finding similarly detailed allegations sufficient to meet the pleadings standard under Rule 9 because “the circumstances of the fraud [are] pled with enough specificity to put defendants on notice as to the nature of the claim.”).

2. Standing Under the FDUTPA

West Boca alleges it is a “person” within the meaning of Section 501.203(6) of the FDUTPA. Doc. #: 385 at ¶899. Manufacturer Defendants argue that West Boca “is not a ‘consumer’ of any medicine sold by Manufacturer Defendants” and “does not allege facts showing that it was involved in a consumer transaction.” Doc. #: 691-1 at 9; Case No. 18-op-45530, Doc. #: 55 at 12. Distributor Defendants argue West Boca doesn’t allege they were involved in “trade or commerce,” Doc. #: 684-1 at 24, and Pharmacy Defendants argue West Boca hasn’t identified whether it purchased an opioid from any Defendant. Doc. #: 686-1 at 8. Having carefully considered each of Defendants’ arguments, the Court finds that West Boca

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has sufficiently established it is a proper party to bring this FDUTPA action.

Prior to 2001, the FDUTPA limited the class of plaintiffs who could file suit to “consumers who have suffered a loss as a result of [the Act].” See [Fla. Stat. § 501.211\(2\)](#); [Bailey v. St Louis](#), 196 So. 3d 375, 382 (Fla. 2d DCA 2016). In 2001, the Florida legislature amended the statute to replace the word “consumer” with the term “person,” thereby giving non-consumers standing to sue. See *id.* A Florida appellate court has confirmed that “[t]his change indicates that the legislature no longer intended the FDUTPA to apply to only consumers, but to other entities able to prove the remaining elements of the claim as well.” [Caribbean Cruise Line, Inc. v. Better Bus. Bureau of Palm Beach Cty., Inc.](#), 169 So.3d 164, 169 (Fla. 4th DCA 2015).

This Court chooses to follow the majority of recent opinions from Florida’s District Courts of Appeal concluding that, “in amending the Act, the legislature intended to give non-consumers standing.” [Collier HMA Physician Mgmt, LLC v. NCH Healthcare Sys., Inc.](#), 2019 WL 277733, at *11 (M.D. Fla., Jan. 22, 2019) (citing [Bailey](#), 196 So. 3d at 383); see also [Off Lease Only, Inc. v. LeJeune Auto Wholesale, Inc.](#), 187 So. 3d 868, 869 n. 2 (Fla. 3d DCA 2016) (same); [Caribbean Cruise Line](#), 169 So. 3d at 169; [Wallace v. Southern Cable Sys., LLC](#), 2016 WL 9308535, at *2 (N.D. Fla. Nov. 4, 2016) (collecting cases) (the FDUTPA “is not limited to consumers, but, rather, it applies to all individuals and entities that are able to prove the three elements on a FDUTPA claim”) (citations omitted); [Stewart Agency Inc. v. Arrigo Enterprises, Inc.](#), 266 So.3d 207, 212 (Fla. 4th DCA 2019) (“an entity does not have to be a consumer to bring a FDUTPA claim, but it still must prove the elements on the claim, including an injury to a consumer”).

Furthermore, West Boca itself need not be involved in a “consumer transaction,” because the FDUTPA is not limited to purely consumer transactions. Instead, it applies to “any act or practice occurring ‘in the conduct of any...commerce.’” [Beacon Property Mgt., Inc. v. PNR, Inc.](#), 890 So.2d 274, 278 (Fla. Dist. Ct. App. 2004) (citation omitted). A plaintiff need not be party to any consumer transaction to bring a FDUTPA claim. See, e.g., [BPI Sports, LLC v. Labdoor, Inc.](#), 2016 WL 739652, at *5 (S.D. Fla. Feb. 25, 2016) (even though the plaintiff admitted it was not a party to any consumer transaction,

the case survived a motion to dismiss and the court analyzed the remaining elements of the FDUTPA claim). Because the FDUTPA is intended to be construed liberally, applies to non-consumers, and does not require a consumer transaction between West Boca and the Defendants, the Court concludes West Boca has standing to assert its FDUTPA claim.

3. Allegations of Unfair and Deceptive Acts

*21 Federal Courts in the Southern District of Florida have held that a “deceptive act” is one where a “representation, omission, or practice occurred that was likely to mislead the consumer acting reasonably in the circumstances, to the consumer’s detriment;” and an “unfair practice” is one that “offends established public policy and ... is immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers.” [Cox v. Porsche Fin. Serv., Inc.](#), 342 F.Supp.3d 1271, 1286 (S.D. Fla. 2018) (internal citations omitted). Courts have defined “trade or commerce” as “the advertising, soliciting, providing, offering, or distributing...any good or service, or any property, whether tangible or intangible, or any other article, commodity, or thing of value, wherever situated.” [Nazario v. Prof'l Account Servs., Inc.](#), No. 2:16-cv-772, 2017 WL 1179917, at *4 (M.D. Fla., Mar. 30, 2017).

West Boca alleges that “each of the Defendants have engaged in unfair and/or deceptive trade practices” in commerce, in violation of the FDUTPA, by omitting the material fact of its failure to design and operate a SOMS, as well as by failing to actually disclose suspicious orders. Doc. #: 385 at ¶902. West Boca also alleges that “Defendants, individually and acting through their employees and agents, and in concert with each other, knowingly made material misrepresentations and omissions of facts to Plaintiff to induce it to purchase, administer, and consume opioids,” and such false or misleading statements violate the FDUTPA. Doc. #: 385 at ¶¶905-06. Each Defendant argues that West Boca cannot meet the first element of proving an FDUTPA claim because it failed to properly plead a “deceptive act.”

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A. Marketing Defendants

West Boca alleges the Marketing Defendants have each engaged in unfair and deceptive acts or practices in commerce by actively promoting and marketing the use of opioids for indications not federally approved, circulating false and misleading information concerning opioids' safety and efficacy, and downplaying or omitting the risk of addiction arising from their use. Doc. #: 385 at ¶901.

Marketing Defendants argue that Florida law provides a "safe harbor" from FDUTPA claims, which they fall within: FDUTPA does not apply to any "act or practice required or specifically permitted by federal or state law." *Fla. Stat. § 501.212(1)*. Manufacturer Defendants bear the burden of establishing the applicability of the safe-harbor provision in a FDUTPA claim, and must show that a specific federal or state law affirmatively authorized it to engage in the conduct alleged.  *Anheuser-Busch Cos.*, 43 F.Supp.3d at 1343 (citing  *Florida v. Tenet Healthcare Corp.*, 420 F.Supp.2d 1288, 1310 (S.D. Fla. 2005)). Manufacturer Defendants argue that, since "the FDA has approved most of the ER/LA [extended release / long-acting] opioid medications at issue here for the treatment of chronic pain and Florida law authorizes such use of opioids," the safe-harbor provisions of the FDUTPA apply and West Boca's claim must fail. Doc. #: 691-1 at 9.

West Boca alleges Manufacturer Defendants' misrepresentations and omissions regarding the risk of opioid use fall into nine "categories of falsehoods," which include misrepresentations regarding: (i) addiction risk; (ii) ease of withdrawal; and (iii) improved patient functionality with long-term use. See Doc. #: 385 at ¶¶146-317. West Boca argues these misrepresentations and omissions are not based on any of the Manufacturer Defendants' proffered "FDA determinations about opioid safety and effectiveness," and thus are not "specifically permitted by federal or state law." Doc. #: 806 at 65-66. West Boca concludes therefore, that the safe-harbor provision does not apply.

*22 The Court finds that the Manufacturer Defendants' have not met their burden. The Manufacturers do not provide unambiguous evidence showing that their methods of promoting and marketing opioids remained within the parameters specifically authorized by state or federal law. See Case No. 18-op-45530, Doc. #: 55 at 17.⁴⁰ The Manufacturer Defendants have not established that the safe-harbor provision of the FDUTPA applies to their

challenged conduct as a matter of law, and the FDUTPA claim will not be dismissed on this ground. See  *Prohias v. AstraZeneca Pharmaceuticals, L.P.*, 958 So.2d 1054, 1056 (Fla. Dist. Ct. App. 2007) (the moving party in an FDUTPA case must "demonstrate that a specific federal or state law affirmatively authorized it to engage in the conduct alleged in the Complaints").

B. Supply Chain Defendants

West Boca alleges that Distributor and Pharmacy Defendants "knowingly made material misrepresentations and omissions of facts to Plaintiff to induce it to purchase, administer, and consume opioids," and "engaged in unfair and/or deceptive trade practices by omitting the material fact of its failure to design and operate a SOMS, and by failing to actually disclose such suspicious orders," as required under the CSA. Doc. #: 385 at ¶¶902; 905; 906.

i. Deceiving Customers

Distributor Defendants argue the Complaint is "entirely devoid" of any allegation that West Boca, "let alone any consumer – was likely to be deceived by Distributors' alleged omission and reporting failures." Doc. #: 684-1 at 25. West Boca's Complaint, however, specifically contains allegations that "Defendants recklessly disregarded the falsity of their representations and omissions," intending that West Boca and others would rely upon them, and "[b]y reason of their reliance on Defendants' misrepresentations and omissions of material fact, Plaintiff, physicians, patients, and/or others suffered actual pecuniary damage." Doc. #: 385 at ¶¶908-911. More specifically, West Boca alleges "Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under federal law [to report and halt suspicious orders of opioids] and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public regarding the Distributor Defendants' compliance with their legal duties." Doc. #: 385 at ¶649. At this stage, it is sufficient that West Boca plausibly alleges the public was misled;

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whether West Boca, regulators, or the public was actually deceived by the alleged false statements is a factual question not properly resolved in a motion to dismiss. *See Schojan v. Papa John's Int'l, Inc.*, 2014 WL 6886041, at *6 (M.D. Fla., Dec. 8, 2014) (denying defendant's motion to dismiss because "[w]hether particular conduct constitutes an unfair or deceptive trade practice is a question of fact"). Therefore, West Boca has properly pled that the Distributors' failure to report suspicious orders could plausibly have deceived it and/or the public.⁴¹

and 501.204. One such allegation reads: "members of the supply chain joined and conspired in the false and deceptive marketing of prescription opioids, which was designed dramatically to increase the demand for and sale of opioids and opioid prescriptions." Doc. #: 385 at ¶14; *see also* Doc. #: 385 at Section XV (alleging facts pertaining to substantive RICO violations, including mail and wire fraud). West Boca also alleges that, while conducting these activities, "[a]ll Defendants engaged in '[t]rade or commerce' within the meaning of Fla. Stat. § 501.203(8)." Doc. #: 385 at ¶900. The Court finds that West Boca has sufficiently alleged unfair or deceptive acts against each of the Defendants.

ii. CSA Violations: Actionable under the FDUTPA

*23 Distributor Defendants assert that violations of the CSA cannot serve as a predicate for an FDUTPA claim because the CSA does not proscribe "unfair methods of competition, or unfair, deceptive, or unconscionable acts or practices," and any CSA violation did not occur in the conduct of "trade or commerce." Doc. #: 684-1 at 24-25.⁴² Distributor and Pharmacy Defendants argue for dismissal, claiming "the only deceptive or unfair act or practice asserted against [Pharmacy Defendants] is a supposed failure to disclose alleged noncompliance with [CSA] regulatory reporting requirements." *See e.g.* Doc. #: 825 at 13.

West Boca incorporates by reference arguments made by Broward County in its opposition to Defendants' motions to dismiss its FDUTPA Claim – that is, the CSA is considered a consumer protection law. In its opposition, Broward County asserts that "[t]he FDCA, which incorporates the CSA, proscribes deceptive and unfair practices, as its purpose is 'to protect the public health, safety, and welfare' [of consumers]."⁴³ Doc. #: 730 at 47. Broward County further asserts that the Defendants' failure to operate a system to disclose suspicious orders of controlled substances "offends established public policy," and is therefore actionable under the FDUTPA. Doc. #: 730 at 47-48.

Whether violations of the CSA serve as an appropriate predicate is not dispositive of West Boca's FDUTPA claim.⁴⁴ The Court finds that West Boca has plausibly alleged "unconscionable, deceptive, or unfair acts or practices" by Distributor Defendants other than those acts that allegedly violate the CSA. *Fla. Stat. §§ 501.202(2)*

C. Causation

*24 Section 501.211(2) of the FDUTPA provides that a "person who has suffered a loss as a result of a violation [of the statute] may recover actual damages." To prove the causation element of a consumer claim under the FDUTPA, West Boca must show that "the practice was likely to deceive a consumer acting reasonably in the same circumstances." *Office of Attorney Gen. v. Bilotti*, 267 So.3d 1, 3 (Fla. 4th DCA 2019) (citation omitted). West Boca "need not prove reliance on the allegedly false statement...but rather a plaintiff must simply prove that an objectively reasonable person would have been deceived." *Cold Stone Creamery, Inc. v. Lenora Foods I, LLC*, 3691 F.App'x 565, 567 (11th Cir. 2009); *see Lombardo v. Johnson & Johnson Consumer Cos. Inc.*, 124 F.Supp.3d 1283, 1290 (citation omitted). Nonetheless, "causation must be direct, rather than remote or speculative." *Lombardo*, 124 F.Supp.3d at 1290 (citation omitted).

Defendants each argue that West Boca has not sufficiently pled the existence of an actionable misrepresentation or omission which would establish causation. (*See* Doc. #: 691-1 at 16; Doc. #: 684-1 at 12-13; Doc. #: 686-1 at 8 (incorporating Doc. #: 582-1 at 3-5)). In response, West Boca asserts that Defendants deceived not only regulators, but also the general public. West Boca alleges that "[p]ublic statements by the [Manufacturer and Distributor] Defendants and their associates created the false and misleading impression to regulators, prescribers, **and the public** that the Defendants rigorously carried out their legal duties...and further created the false impression

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that these Defendants also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.” Doc. #: 385 at ¶616 (emphasis added). Furthermore, West Boca alleges that, “[i]n addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook **to fraudulently convince the public** that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.” Doc. #: 385 at ¶655 (emphasis added). Lastly, West Boca alleges that Supply Chain Defendants, which include the Pharmacies, had unlawful “policies and practices [which] remained in place even as the [opioid] epidemic raged,” Doc. #: 385 at ¶676, and that “members of the supply chain joined and conspired in the false and deceptive marketing of prescription opioids, which was designed dramatically to increase the demand for and sale of opioids and opioid prescriptions” to the medical community and the public. Doc. #: 385 at ¶14.

The Court concludes West Boca has plausibly alleged that deceptive practices undertaken by all Defendants worked to deceive both regulators and the public, including West Boca, in a manner specifically designed to increase the Defendants’ ability to manufacture, distribute, and sell more prescription opioids. The resultant increase in Defendants’ commercial transactions were allegedly legitimized by Defendants’ deceptive practices, and created the opioid epidemic which injured West Boca. This causal chain is consistent with that described elsewhere in this opinion and the Court’s prior opinions. See Sec. IV.A., *infra*; Doc. #: 1203; 3177. Therefore, West Boca has plausibly alleged that actions taken by each Defendant were objectively likely to deceive a reasonable person and caused West Boca’s asserted injuries. Defendants’ Motions to Dismiss on this ground are denied.⁴⁵

4. Actual Damages

*25 The FDUTPA provides that, “[i]n any action brought by a person who has suffered a loss as a result of a violation of [the Act], such person may recover actual damages, plus attorney’s fees and court costs.” § 501.211(2). Actual damages are limited to compensatory damages; consequential damages are not available under

the Act. *Dorestin v. Hollywood Imports, Inc.*, 45 So.3d 819 (Fla. 4th DCA 2010). In addition, the FDUTPA affords civil private causes of action for equitable relief in the form of a declaratory judgment or an injunction. See *Nazario*, 2017 WL 1179917, at *4.

First, Defendants insist West Boca hasn’t alleged “actual damages” cognizable under Section 501.207(1) of the FDUTPA, arguing damages are defined as “the difference in the market value of the product or service in the condition in which it was delivered and its market value in the condition in which it should have been delivered.” See, e.g., Doc. #: 582-1 at 14 (incorporated by reference). While this is true, “the inclusion of diminished value as an actual damage under the FDUTPA is **an addition** to those damages that are already easily recognized as actual damages,” that is, the “amounts necessary to compensate adequately an injured party for losses sustained as the result of a defendant’s wrongful or negligent actions.” See *Diamond v. Porsche Cars N. Am., Inc.*, 2012 WL 6837916, at *4-5 (Cir. Ct. Fla. Sept. 28, 2012) (citation omitted). West Boca has alleged adequately these other types of compensatory damages.

Defendants also argue West Boca has not alleged a cognizable damages claim because “its purported damages arise from personal injuries.” See, e.g. Doc. #: 684-1 at 26. The Court concluded above, in Section IV.B., that West Boca’s being in the business of providing healthcare services, does not make its injuries “derivative” of personal injuries.

Defendants make additional arguments, but the Court need not undertake an itemized evaluation of the validity of each type of claimed damages on a motion to dismiss, so long as some alleged damages are sufficient to support West Boca’s claim. It remains West Boca’s burden to prove at trial that the damages presented are actual, quantifiable damages. See *State Farm*, 315 F.Supp.3d at 1311 (“[a]ll questions regarding the reasonableness and quantification of damages are generally issues of fact...[and] should be left to the jury”) (citation omitted). But West Boca’s pleading of alleged damages is sufficient. Defendants’ Motions to Dismiss are denied on these grounds.

5. Equitable Relief

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Regardless of whether a plaintiff can recover “actual damages” under [Section 501.211\(2\)](#), it may obtain injunctive relief under [Section 501.211\(1\)](#). See [Ahearn v. Mayo Clinic](#), 180 So.3d 165, 172 (1st DCA Fla. 2015) (citation omitted). To state a claim for equitable relief, West Boca “must show (1) that it is aggrieved, in that its rights have been, are being, or will be adversely affected, by (2) a violation of FDUTPA, meaning an unfair or deceptive practice which is injurious to consumers.” [Fla. Stat. § 501.211\(1\)](#); [Stewart Agency, Inc.](#), 266 So.3d at 214. The equitable relief available under FDUTPA is limited to a declaratory judgment or an injunction. [Fla. Stat. § 501.211](#).

West Boca has asked the Court for “equitable relief, including injunctive relief,” alleging specific examples of how West Boca “continues to suffer from the unlawful actions by the Defendants.” See Doc. #: 385 at ¶¶10; 748; 769. Defendants do not specifically address West Boca’s requests for equitable relief. Absent briefing to the contrary, the Court concludes West Boca has shown “a sufficient likelihood that [it] will be affected by the allegedly unlawful conduct in the future.” [Houston v. Marod Supermarkets, Inc.](#), 733 F.3d 1323, 1328-29 (11th Cir. 2013). West Boca may seek equitable relief under the FDUTPA.

ascertained, to be untrue or misleading, and which are or were so made or disseminated with the intent or purpose, either directly or indirectly, or selling or disposing of real or personal property, services of any nature whatever, professional or otherwise, or to induce the public to enter into any obligation relating to such property or services.

[Fla. Stat. § 817.40\(5\)](#).

To prove misleading advertising under Florida law, a plaintiff must “prove reliance on the alleged misleading advertising, as well as each of the other elements of the common law tort of fraud in the inducement.” [Koens v. Royal Caribbean Cruises, Ltd.](#), 774 F.Supp.2d 1215, 1220 (S.D. Fla. 2011) (citation omitted).

West Boca alleges Marketing Defendants’ advertising was misleading in the following ways:

- a. Misrepresenting the truth about how opioids lead to addiction;
- b. Misrepresenting that opioids improve function;
- c. Misrepresenting that addiction risk can be managed;
- d. Misleading doctors, patients, and payors through the use of misleading terms like “pseudoaddiction;”
- e. Falsey claiming that withdrawal is simply managed;
- f. Misrepresenting that increased doses pose no significant additional risks;
- g. Falsey omitting or minimizing the adverse effects of opioids and overstating the risks of alternative forms of pain treatment.

Doc. #: 385 at ¶919.

Marketing Defendants argue West Boca has failed to allege any false or misleading statement and failed to allege it was exposed to, and relied upon, any alleged misrepresentation by Marketing Defendants.⁴⁶ Doc. #:

any statements made, or in oral, written, or printed form or otherwise, to or before the public, or any portion thereof, which are known, or thorough the exercise of reasonable care or investigation could or might have been

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691-1 at 11. But this is plainly incorrect. West Boca identifies specific examples of allegedly-misleading statements made by Marketing Defendants, setting forth nine “falsehoods” Marketing Defendants promoted to increase the market for opioids. *See* Doc. #: 385 at ¶¶155-327. West Boca also identifies the “multiple channels” Marketing Defendants used to disseminate these allegedly misleading statements. *See* Doc. #: 385 at ¶¶328-480. In fact, West Boca dedicates over 300 paragraphs of its Complaint to specifically identifying documents or statements it believes were misleading, the source of the statements, the various methods used to disseminate the statements, and when and to whom the statements were made. *See* Doc. #: 385 at ¶¶155-480.⁴⁷ *See also Doria v. Royal Caribbean Cruises, Ltd.*, 393 F.Supp.3d 1141, 1145 (S.D. Fla. 2019) (finding plaintiff’s allegations met the heightened pleading standard of Rule 9(b), as it provided the statements alleged to be misleading or false, the sources of the misleading materials, and identified when the misleading statements were made.) The Court has previously concluded that, “where multiple defendants are alleged to have engaged in the same pattern of conduct,” a plaintiff need not “reiterate its allegations against each defendant individually.” Doc. #: 1499 at 25-26 (adopted by Doc. #: 1680 at 5). “Such a finding would exponentially increase the length of pleadings while adding no substantive value.” Doc. #: 1499 at 26. West Boca’s allegations are sufficient, even under the heightened pleading standard of Rule 9.

*27 West Boca has also sufficiently alleged throughout its Complaint that it relied upon Marketing Defendants’ allegedly misleading advertisements. Accordingly, this Court finds that West Boca has stated a claim for Misleading Advertising, and Marketing Defendants’ Motion to Dismiss is denied on this ground.

VIII. Breach of Implied Warranty of Fitness For a Particular Purpose

West Boca alleges each Defendant breached implied warranties of fitness for a particular purpose, in violation of Fla. Stat. Ann. §§ 672.315 (the “Florida UCC”).⁴⁸ Doc. #: 385 at ¶¶922-928. West Boca alleges Defendants knew or had reason to know that: (i) West Boca was purchasing opioids “for a particular purpose, namely to provide pain

relief in an appropriate way that did not unnecessarily endanger its patients if the opioids were used as sold and marketed by Defendants;” and (ii) “[t]he opioids that Plaintiff purchased were not suitable for the particular purpose for which Plaintiff purchased them.” West Boca claims it suffered damages as a result of justifiably relying upon Defendants’ “skill, judgment and narrative to provide opioids that were suitable.” Doc. #: 385 at ¶¶924-28.

However, West Boca’s opposition brief is entirely devoid of any factual statements or legal arguments regarding a breach of warranty. Doc. #: 806. As Defendants correctly argue, a plaintiff abandons its claims by failing to raise them in its brief opposing a defendant’s motion to dismiss. *See, e.g.* Doc. #: 55 at 14 (citing *Doe v. Bredesen*, 507 F.3d 998, 1007 (6th Cir. 2007)). Therefore, the Court finds that West Boca has abandoned its breach of implied warranty claim. Defendants’ Motions to Dismiss Count V are granted.⁴⁹

IX. Negligence

West Boca asserts five variations of negligence claims: Negligence (Count VI); Wanton Negligence (Count VII); Negligence Per Se (Count VIII); Negligent Marketing (Count IX); and, Negligent Distribution (Count X). The Court examines each claim separately.

A. Common-Law Negligence

There are four elements to a common-law negligence claim under Florida law: (1) a duty, or obligation, recognized by the law, requiring the defendant to conform to a certain standard of conduct, for the protection of others against unreasonable risk; (2) breach of that duty; (3) a reasonably close causal connection between the conduct and the resulting injury, or “proximate cause;” and (4) damages. *See Clay Elec. Co-op., Inc. v. Johnson*, 873 So. 2d 1182, 1185 (Fla. 2003). In its Sixth Claim for Relief, West Boca alleges each Defendant breached “its duty to exercise reasonable care in the manufacturing, marketing, selling, and distributing of highly dangerous opioid drugs.” Doc. #: 385 at

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¶¶930-931. West Boca further alleges that, “[a]s a proximate result, Defendants have caused Plaintiff’s injury related to the treatment of opioid-related conditions.” Doc. #: 385 at ¶¶933. Defendants only challenge the sufficiency of the allegations with respect to the duty of care.⁵⁰ See Doc. #: 691-1 at 14-15; Doc. #: 684-1⁵¹ at 19-20; Doc. #: 686-1 at 4.

*28 In Florida, “[t]he touchstone for determining whether a duty exists is ‘foreseeability.’ ‘[W]here a person’s conduct is such that it creates a “foreseeable zone of risk” posing a general threat of harm to others, a legal duty will ordinarily be recognized to ensure that the underlying threatening conduct is carried out reasonably.’” *Sewell v. Racetrac Petroleum, Inc.*, 245 So. 3d 822, 825 (Fla. Dist. Ct. App. 2017) (citing *McCain v. Florida Power Corp.*, 593 So.2d 500, 503 (Fla. 1992); *Williams v. Davis*, 974 So.2d 1052, 1056 (Fla. 2007)); see also *U.S. v. Stevens*, 994 So.2d 1062, 1066-67 (Fla. 2008). In order to determine whether a duty arises, the Florida Supreme Court has identified four sources that provide such a duty: “(1) legislative enactments or administration regulations; (2) judicial interpretations of such enactments or regulations; (3) other judicial precedent; and (4) a duty arising from the general facts of the case.” *Clay Elec.*, 873 So. 2d at 1185 (quoting *McCain*, 593 So.2d at 503 n.2).

West Boca relies upon the general facts of this case as the source of Defendants’ common-law duty. See Doc. #: 806 at 41-42. West Boca asserts its injuries were within the “foreseeable zone of risk” created by Defendants’ manufacturing, distributing, and dispensing activities, because: (a) if not conducted with a requisite level of care, these activities could (and, in fact, did) foreseeably allow opioids to be diverted in large quantities into West Boca’s service area; (b) this diversion could (and, in fact, did) foreseeably lead to widespread injury to people’s health, creating a public health crisis; and (c) hospitals are necessarily and foreseeably on the “front lines” of any and all health crises. See Doc. #: 806 at 41 (citing Doc. #: 385 at ¶¶16-17; 47; 58; 60). West Boca alleges that, not only could the Defendants have reasonably foreseen that hospitals would bear the responsibility for treating individuals with opioid addiction, but the Defendants may have even counted on it -- West Boca alleges “defendants knew that but for West Boca’s providing at least some aspect of a safety net, the number of overdose deaths and other related health consequences arising from opioid addictions would have even been far greater than actually

occurred.” Doc. #: 385 at ¶19. Although this allegation will need to be proved, it is taken as true at the motion to dismiss stage.

The Court concludes West Boca’s asserted injuries plausibly fall within the foreseeable zone of risk created by Defendants’ manufacturing, distributing, and dispensing activities related to opioid drugs. In other words, Defendants’ activities regarding these potentially dangerous and highly addictive opioid drugs create a “general threat of harm to others,” and it is therefore appropriate, under Florida law, to recognize a legal duty “to ensure that the underlying threatening conduct is carried out reasonably.” *Sewell*, 245 So. 3d at 825. At this stage in the case, a complaint need only set forth a plausible claim for relief and should not be dismissed unless it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations. *Trollinger*, 370 F.3d at 615; *Krehling v. Baron*, 900 F.Supp. 1574, 1577 (M.D. Fla. 1995). Thus, the Court finds West Boca has sufficiently pled that Defendants owe it a duty of care. Defendants Motion to Dismiss Count VI is denied.

B. Wanton Negligence Allegations Against All Defendants

In the Seventh Claim for Relief, West Boca alleges Wanton Negligence. West Boca alleges:

Defendants conducted themselves with reckless indifference to the consequences of their acts and omissions, in that they were conscious of their conduct and were aware, from their knowledge of existing circumstances and conditions, that their conduct would inevitably result in injury to others, specifically hospitals such as Plaintiff, which would be subject to providing unreimbursed healthcare treatment to patients with opioid conditions.

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*29 Doc. #: 385 at ¶938.

Distributor Defendants argue that willful and wanton negligence is considered a “more culpable” form of misconduct than ordinary negligence, as it relates to “conduct which is more in the nature of an intentional wrong.” Distributor Defendants assert West Boca’s allegations do not even support a simple negligence claim, and therefore cannot support a claim for wanton negligence. Doc. #: 684-1 at 30. Manufacturer Defendants argue that West Boca did not properly plead its negligence claim to allege Manufacturer Defendants owed it a duty of care. Doc. #: 691-1 at 14.⁵²

Under Florida law, conduct rises to the level of willful and wanton misconduct when the actor has “knowledge, actual or constructive, of the likelihood that his conduct will cause injury to other persons” and this conduct “indicate[s] a reckless indifference to the rights of others.” *Bell v. Circle K Stores Inc.*, No. 8:18-cv-1296, 2019 WL 5190907, at *4 (M.D. Fla. Oct. 15, 2019) (citing *Boyce v. Pi Kappa Alpha Holding Corp.*, 476 F.2d 447, 452 (5th Cir. 1973)). Reckless misconduct differs from negligence in that “reckless misconduct requires a conscious choice of a course of action...with knowledge of the serious dangers to others involved in it or with knowledge of facts which would disclose the danger to any reasonable man.” *Id.* (citing *Restatement (Second) of Torts* § 500).

As outlined in the RICO section of this Order, the Complaint details the alleged manner in which Defendants knowingly promoted and distributed misleading and false information in order to increase the market for prescription opioids, and willfully failed to monitor, report, or halt shipments of suspicious orders of opioids. West Boca’s Complaint sets forth alarming statistics related to the opioid epidemic, further alleging each Defendant was aware of, yet ignored, these statistics. See Doc. #: 385 at ¶¶1-50. West Boca also alleges the Defendants’ conduct “continued in the face of numerous enforcement actions, fines, and other warnings from state and local governments and regulatory agencies,” and that “Defendants paid their fines, made promises to do better, and continued on with their marketing and supply schemes.” Doc. #: 385 at ¶783.

The Court concludes these factual allegations, taken as true, rise to the level of reckless indifference. West Boca has adequately pled allegations against Defendants which reflect intentional misconduct and could ultimately, if proved, support a finding of wanton negligence against

Defendants. Therefore, Defendants’ Motion to Dismiss the wanton negligence claim is denied.

C. Negligence Per Se Allegations Against All Defendants

*30 In the Eighth Claim for Relief, West Boca alleges negligence per se, claiming Defendants violated their duties under the CSA by “knowingly or intentionally furnishing false or fraudulent information in, and/or omitting material information from, documents filed with the DEA.” Doc. #: 385 at ¶942. West Boca also alleges “Defendants failed to comply with the FDCA” in failing “to provide effective controls and procedures to guard against diversion of controlled substances in contravention of Florida and federal law.” Doc. #: 385 at ¶¶944; 948.

The Defendants argue that neither the CSA nor the FDCA establish a private right of action, so West Boca cannot pursue a negligence per se claim premised on these statutes. See Doc. #: 684-1 at 27-28; Doc. #: 691-1 at 14-15. The Court agrees with Defendants.

As this Court has ruled previously, “[t]he CSA was intended to protect individual members of the public from falling victim to drug misuse and abuse.” See Doc. #: 1680 at 24; Doc. #: 3177 at 53. West Boca, a hospital system, is not an “individual member of the public” that could fall victim to drug misuse and abuse. West Boca is not an intended beneficiary of the CSA. See Doc. #: 3177 at 53. Nor is West Boca the intended beneficiary of the FDCA, which was enacted to “[s]afeguard the public health and promote the public welfare by protecting the public from injury” caused by using products relating to drugs, devices and cosmetics. See  § 499.002(1), Fla. Stat. (1993);  *Fields v. Mylan Pharm's Inc.*, 751 F.Supp.2d 1257, 1259 (N.D. Fla. 2009). Furthermore, under Florida law, negligence per se cannot be premised upon a violation of the CSA or the FDCA, as there is no “evidence of a legislative intent to create a private cause of action.” *Rowe v. Mentor Worldwide, LLC*, 297 F.Supp.3d 1288 (M.D. Fla. 2018).

For these reasons, West Boca has failed to state a claim for negligence per se. Defendants’ Motion to Dismiss is granted, and Count VIII is dismissed.

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D. Negligent Marketing Allegations Against Marketing Defendants

In the Ninth Claim for Relief, West Boca alleges “negligent marketing” against Marketing Defendants, claiming they “marketed opioids in an improper manner” by overstating the benefits of chronic opioid therapy and opioids’ superiority compared with other treatments. Doc. #: 385 at ¶973(a) and (c). West Boca alleges Marketing Defendants also mischaracterized the serious risks and adverse outcomes of opioid use, including the “serious risk of addiction, overdose and death,” the difficulty of withdrawal from opioids, and West Boca contends that opioids were marketed for indications and benefits that were outside of the opioids’ labels and not supported by substantial evidence. Doc. #: 385 at ¶973(b), (d)-(e). West Boca also alleges the Marketing Defendants “knew or should have known that opioids were unreasonably dangerous and cause addiction” when used to treat chronic pain. Doc. #: 385 at ¶977.

Manufacturing Defendants argue that a claim for “negligent marketing” does not exist under Florida law and cannot serve as an independent cause of action. Doc. #: 691-1 at 14. West Boca responds that several courts in Florida have recognized negligent marketing claims. However, the case law cited by West Boca does not support this argument. See Doc. #: 806 at 45.⁵³ While there is Florida case law to support “fraudulent marketing” or “negligent misrepresentation” claims against drug manufacturers, see, e.g., *Hamblen v. Davol, Inc.*, 2017 WL 6406888, at *3 (M.D. Fla. Dec. 15, 2017) (denying motion to dismiss plaintiff’s negligent misrepresentation claim alleging manufacturer of hernia patch omitted information about the risks of its product), Florida courts have not yet deemed “negligent marketing” a separate cause of action.⁵⁴

*31 For these reasons, West Boca has failed to state a viable claim for negligent marketing. Marketing Defendants’ Motion to Dismiss is granted with respect to Count IX.

E. Negligent Distribution Allegations Against All Defendants

In the Tenth Claim for Relief, West Boca alleges “Negligent Distribution” against all Defendants, alleging they “distributed opioids in an improper manner” when they failed to maintain effective controls against diversion of opioids, (i.e. failed to monitor, report, or stop or suspend shipments of suspicious orders). West Boca alleges Defendants distributed and sold “opioids in a way that facilitated and encouraged their flow into the illegal, secondary market” (i.e. “knew or should have known they were distributing and selling opioids prescribed by ‘pill mills.’ ”). Doc. #: 385 at ¶986.

Similar to Count IX, Manufacturing and Pharmacy Defendants argue that “negligent distribution” claims do not exist in Florida law, Doc. #: 691-1 at 14; Doc. #: 686-1 at 4. Distributor Defendants argue West Boca’s negligent distribution claim “is entirely duplicative of its negligence claim,” and therefore, fails. Doc. #: 684-1 at 21-22.

As with West Boca’s negligent marketing claim, there is no specific case law holding that a negligent distribution claim against a pharmaceutical distributor exists under Florida law. Thus, for the same reasons as with Count IX, West Boca has failed to state a viable claim for negligent distribution. Defendants’ Motion to Dismiss is granted with respect to Count X.

X. Unjust Enrichment

In the Twelfth Claim for Relief, West Boca alleges unjust enrichment against all Defendants, claiming “Plaintiff provided unreimbursed healthcare treatment to patients with opioid conditions that Defendants are responsible for creating,” and West Boca thereby conferred a benefit on Defendants. Doc. #: 385 at ¶1006. West Boca also argues it was a “purchaser and dispenser of opioids which conferred pecuniary benefits upon the Defendants.” Doc. #: 806 at 51-52; 58. West Boca alleges it would be “inequitable for Defendants to retain the benefit without payment of its value” and Defendants must disgorge their unjustly acquired profits by providing restitution to West Boca. Doc. #: 385 at ¶¶1008-11.

In Florida, the elements of unjust enrichment are: (1) plaintiff has conferred a benefit on the defendant, who has knowledge thereof; (2) defendant voluntarily accepts and

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retains the benefit conferred; and (3) the circumstances are such that it would be inequitable for the defendant to retain the benefit without first paying the value thereof to the plaintiff. See *Duty Free World, Inc. v. Miami Perfume Junction, Inc.*, 253 So.3d 689, 693 (Fla. 3d DCA 2018). The basis of the remedy for unjust enrichment is to provide restitution where one person has been unjustly enriched at the expense of another. See *id.* Disgorgement is an equitable remedy in unjust enrichment actions, and is measured by the defendant's ill-gotten gains rather than the plaintiff's losses. See, e.g., *S.E.C. v. Levin*, 849 F.3d 995, 1006 (11th Cir. 2017).

Defendants argue that West Boca does not plausibly allege any benefit it conferred upon the Defendants, arguing West Boca only conferred benefits upon its patients. See Doc. #: 691-1 at 17; Doc. #: 684-1 at 22-23. Distributors further argue that: (1) West Boca fails to allege the Distributors were aware of the benefit conferred upon them; (2) the unjust enrichment claim fails because it is duplicative, as it is based on the same alleged conduct underlying its other claims; and (3) because West Boca is obligated under both state and federal law to provide emergency medical care to indigent patients, West Boca's garnering of unreimbursed medical expenses is not unjust. See Doc. #: 684-1 at 22-23.

*32 For the reasons stated in *Summit County*, see Doc. ##: 1025 at 91-95; 1203 at 36-38, and repeated by this Court in *Cleveland Bakers*, see Doc. #: 3177 at 61-63, these arguments do not persuade the Court to dismiss West Boca's unjust enrichment claim. The Ohio law of unjust enrichment parallels Florida law; accordingly, the Court's prior rulings apply here. See  *City of Miami v. Bank of America Corp.*, 800 F.3d 1262, 1288 (11th Cir. 2015).

First, as in the *Summit County* case, West Boca's Complaint pleads a facially plausible unjust enrichment cause of action "on the theory that [the plaintiff] conferred a benefit upon all Defendants by alleging that they paid for the cost of harm caused by the defendant's conduct, i.e., the defendants' externalities." Doc. #: 1025 at 95.³⁵ Furthermore, Defendants' argument that there was no direct transaction between the parties, and therefore no direct benefit conferred, does not warrant dismissal of the unjust enrichment claim under Florida law. See, e.g.,

 *Wilson v. EverBank, N.A.*, 77 F. Supp. 3d 1202, 1236-37 (S.D. Fla. 2015) (citing cases in the Southern District of Florida that permit an unjust enrichment claim to stand where the benefit is conferred through an intermediary); see also  *Sierra Equity Group, Inc. v.*

White Oak Equity Partners, LLC, 650 F.Supp.2d 1213, 1229 (S.D.Fla. 2009) ("Whether [Defendants] did or did not receive a direct benefit from Plaintiff is a question of fact that cannot be resolved at the motion to dismiss stage.").

The Court has also addressed and rejected in its *Summit County* ruling each of the Distributor Defendants' remaining arguments. First, the Court previously ruled that allegations similar to West Boca's allegations herein—that "Defendants appreciated and knew of this benefit"—adequately supports the unjust enrichment element of knowledge in the pleading stage. See Doc. #: 1025 at 94. Second, the argument that West Boca's unjust enrichment claim should be dismissed as "duplicative" was rejected in *Summit County* and is expressly rejected by courts in the Southern District of Florida. See Doc. #: 1025 at 94-95; *In re Monat Hair Care Prods. Marketing, Sales Practices, and Prods. Liab. Litig.*, MDL No. 2841, 2019 WL 5423457, at *5 (S.D. Fla. Oct. 23, 2019) ("The general rule that 'equitable remedies are not available under Florida law when adequate legal remedies exist'...does not apply to unjust enrichment claims.") (citations omitted);  *Martorella v. Deutsche Bank Nat. Trust Co.*, 931 F.Supp.2d 1218, 1227 (S.D. Fla. 2013) (finding plaintiff could "maintain an equitable unjust enrichment claim in the alternative to her legal claims against Defendants").

Finally, Distributor Defendants' argument that "there is nothing unjust" about the costs incurred by West Boca, because it was obligated to provide care to patients adversely affected by opioids, was also rejected in *Summit County*. See Doc. #: 1025 at 94 ("the complaint pleads that the costs Plaintiffs assumed 'are not part of the normal and expected costs' and that 'Defendants' alleged wrongful acts' were not the sort to be reasonably expected"); but see  *City of Miami v. Bank of America Corp.*, 800 F.3d 1262 (11th Cir. 2015) (upholding dismissal of City's unjust enrichment claim, finding it was not clear that the municipal expenditures at issue are "among the types of benefits that can be recovered by unjust enrichment under Florida law").

*33 For these reasons, Defendants' Motion to Dismiss West Boca's unjust enrichment claim is denied.

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XI. Conclusion

Accordingly, Defendants' Motions to Dismiss are **DENIED** with respect to Counts I (RICO ); II (RICO )); III (FDUTPA); IV (Misleading Advertising); VI (Negligence); VII (Wanton Negligence); XI (Nuisance); and XII (Unjust Enrichment).

Defendants' Motions to Dismiss are **GRANTED** with respect to Counts II (RICO )); V (Breach of

Implied Warranty); VIII (Negligence Per Se); IX (Negligent Marketing); and X (Negligent Distribution).

IT IS SO ORDERED.

All Citations

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Footnotes

¹ Unless otherwise indicated, all document numbers refer to the master MDL docket, Case No. 17-md-2804. Page numbers, when necessary, refer to the documents' native format pagination. West Boca's Complaint was refiled unredacted at Doc. #: 2985 and although the Court refers to the sealed complaint, Doc. #: 385, paragraph numbers in the unredacted version should be the same.

² The Distributors' motion was filed collectively by defendants AmerisourceBergen Drug Corporation ("ABDC"); Cardinal Health, Inc. ("Cardinal"); and McKesson Corporation ("McKesson") (collectively, "Distributors" or "Distributor Defendants").

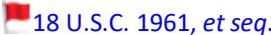
³ The Pharmacies' motion was filed collectively by defendants CVS Health Corporation ("CVS"); The Kroger Co. ("Kroger"); Walgreens Boots Alliance, Inc. ("Walgreens"); and Walmart Inc. ("Walmart") (collectively "Pharmacies" or "Pharmacy Defendants").

⁴ The Manufacturers' motion was filed collectively by defendants Purdue Pharma LP, Purdue Pharma Inc., and The Purdue Frederick Company Inc. ("Purdue"); Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc. ("Allergan"); Watson Laboratories, Inc., Actavis Pharma, Inc.; Actavis LLC; Teva Pharmaceuticals, USA, Inc.; and Cephalon, Inc. ("Teva"); Johnson & Johnson ("J&J") and Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc. ("Janssen"); Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. ("Endo"); Insys Therapeutics, Inc. ("Insys"); Mallinckrodt LLC ("Mallinckrodt"); and Noramco, Inc. ("Noramco") (collectively "Manufacturers" or "Manufacturer Defendants").

⁵ The Court recognizes that some Defendants have or are contemplating filing for bankruptcy protection, and litigation against those Defendants has or may be stayed pending those proceedings. For the sake of simplicity, the Court addresses these motions as they were filed by the parties.

⁶ The Manufacturers' Reply was not filed on the master MDL docket.

⁷ Additionally, on April 5, 2019, various hospital plaintiffs, including West Boca, filed a tangentially-related Brief in Response to Defendants' Briefing on the Viability of Public Nuisance Nationwide. Doc. #: 1523.

⁸ Racketeer Influenced and Corrupt Organizations Act, 

⁹ In its Complaint, West Boca uses the following definitions:

- "Collectively, Purdue, Actavis, Cephalon, Janssen, Endo, Insys, and Mallinckrodt are referred to as 'Marketing

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Defendants.’” See Doc. #: 385 at ¶131. West Boca’s definition of Janssen includes J&J and Noramco, thus the “Marketing Defendants” are the same as the Manufacturers defined in footnote 4 by their joint participation in the Manufacturers’ Motion to Dismiss.

- “Cardinal, McKesson, and AmerisourceBergen are collectively referred to as the ‘Distributor Defendants.’” Doc. #: 385 at ¶148.
- “Collectively, Defendants CVS, Kroger, Rite Aid, Walgreens, and Wal-Mart are referred to as ‘National Retail Pharmacies.’” Doc. #: 385 at ¶154. Although incorporated in this definition, Rite-Aid of Maryland, Inc. was voluntarily dismissed on May 29, 2018. See Case No. 18-op-45530, Doc. #: 5; see also Doc. #: 760 (redacted complaint filed with Rite Aid removed).
- “Additionally, the Distributor Defendants and the National Retail Pharmacies are collectively referred to as the ‘Supply Chain Defendants.’” Doc. #: 385 ¶154.

¹⁰ Those cases are *County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.*, 18-op-45090; *The Muscogee (Creek) Nation v. Purdue Pharma L.P., et al.*, 18-op-45459; and *The Blackfeet Tribe of the Blackfeet Indian Reservation v. AmerisourceBergen Drug Corp., et al.*, 18-op-45749.

¹¹ The Magistrate Judge’s R&R and the Court’s Opinion and Order addressed the then-operative *Summit County* Complaint, Doc. #: 514. This complaint has since been amended. See Doc. ##: 2943; 3020. The *Blackfeet Tribe* Complaint was not filed on the master MDL docket. The referenced Doc. #: 6 corresponds to case no. 18-op-45749.

¹² It seems this third category of damages might be offset entirely by the profit West Boca made on the sale of the opioid medications to patients. At this stage of the litigation, however, the Court accepts that this third category of damages does exist.

¹³ The Court has previously addressed these legal concepts under Ohio and Oklahoma law. See Doc. ##: 1025 at 29-32, 79-82; 1680 at 6-10. Although not dispositive, the analysis remains instructive and is incorporated herein by reference.

¹⁴ It is worth noting as well that in *Benitez v. Standard Havens Prod., Inc.*, 7 F.3d 1561, 1565 (11th Cir. 1993), the case from which the Eleventh Circuit certified the question of whether knowing product misuse was a complete bar to recover on a products liability claim to the Florida Supreme Court, the Eleventh Circuit distinguished  *Clark* as being “based on the particular facts of the case and the lack of causation between any alleged defect and the plaintiff’s injuries, not on an absolute bar to recovery for knowing misuse.” *Benitez*, 7 F.3d at 1565, *certified question answered*, 648 So. 2d 1192 (Fla. 1994).

¹⁵ Additionally, as Broward County points out in its own opposition brief (incorporated by West Boca),  *Labzda* was decided on a full record at summary judgment. Doc. #: 730 at 23 n.16. If the sole proximate cause doctrine did not preclude *Labzda*’s claims on a motion to dismiss, there is no reason to believe dismissal is appropriate here. Causation questions are best left to a jury.  *Simon*, 895 F.2d at 1316.

¹⁶ The injuries asserted by *Summit County* are listed in Doc. #: 1203 at 15-16.

¹⁷ The foreseeability element is evaluated further in the Court’s analysis of West Boca’s negligence claims in Section IX below.

¹⁸ Distributors, for example, assert that “[t]he Hospital’s claimed injuries consist entirely of ‘unreimbursed charges for its treatment of patients.’” Doc. #: 684-1 at 4 (citing Doc. #: 385 at ¶55) (emphasis added). This assertion is plainly inaccurate, as it identifies only the first of the three categories of alleged damages. The Defendants’ failure to argue

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that the second and third categories of alleged damages are not a direct consequence of their conduct leaves the Court with no choice but to conclude its prior analyses in its opinions in *Summit County* and *Cleveland Bakers and Teamsters Health and Welfare Fund, et al.*, Case No. 1:18-op-45432 ("Cleveland Bakers"), remains valid and applicable to West Boca's claims. See Doc. #: 1203; *Opinion and Order Regarding Motions to Dismiss Cleveland Bakers Claims*, Doc. #: 3177. The Court concludes now, as it has before, that the Defendants' alleged behavior—false marketing and/or failure to prevent diversion—led to the opioid crisis, and the opioid crisis led to West Boca's injuries. Thus, West Boca has alleged a foreseeable and sufficiently direct chain of causation to cross the plausibility threshold. See Doc. #: 1203 at 7-10; Doc. #: 3177 at 24-27.

The motion to dismiss standard precludes dismissal if there is any set of facts upon which relief may be available. Because West Boca has alleged a set of facts upon which relief can be granted (relief being compensation for the second and third categories of asserted injuries, for example), the Court will allow West Boca's RICO claim to survive Defendants' motions to dismiss with respect to unreimbursed medical expenses as well. But the Court expects its concerns regarding these different categories of damages, described further below, will be addressed on a more fulsome factual record at summary judgment.

¹⁹ As mentioned below, the Court's concern regarding the viability of the first category of alleged damages attaches to all of West Boca's claims, not just its RICO claims.

²⁰ Distributors rely heavily on *International Brotherhood of Teamsters, Local 734 Health & Welfare Trust Fund v. Philip Morris Inc.*, 196 F.3d 818 (7th Cir. 1999). See Doc. #: 684 at 5-6. *Brotherhood of Teamsters* is even less instructive. Where *Allegheny* and *Washington Public* are hospital cases, *Brotherhood of Teamsters* is a third-party payor case. Furthermore, all three cases arise out of the tobacco litigation. In *Brotherhood of Teamsters*, the Seventh Circuit concluded that "[t]he problem for [the third-party payor plaintiffs] is...that they do not deal with tobacco producers, the supposed wrongdoers." *Id. at 827*. Here, West Boca asserts that it does deal directly with "supposed- wrongdoer" opioid manufacturers. And given the litany of other legal and factual distinctions that, in this Court's view, were not adequately briefed or were overlooked entirely, it is not clear whether or to what extent *Brotherhood of Teamsters* is applicable at all, let alone to the Distributors.

West Boca, on the other hand, relies heavily on *In re Neurontin Marketing and Sales Practices Litig.*, 712 F.3d 21 (1st Cir. 2013). See Doc. #: 806 at 6-7; 12; 16; 18. Unlike the tobacco cases mentioned above, *Neurontin* is a pharmaceutical case and is noteworthy for its acceptance of aggregate evidence to prove RICO causation. While this Court has stated it will allow Plaintiffs to use aggregate evidence to attempt to prove causation in the RICO context, it is also worth noting there are important differences between *Neurontin* and the opioid cases. For example, in *Neurontin*, plaintiff Kaiser used aggregate data to link marketing activity of a *single* manufacturer's *single* drug to a *single* alleged injury (payment for off-label prescriptions) by a *single* plaintiff. The First Circuit concluded that Kaiser's regression analysis, in conjunction with other non-aggregate-data evidence, was sufficient to prove causation and not just correlation. See *Neurontin*, 712 F.3d at 46. In contrast, in the opioid litigation there are *many* manufacturers that marketed *many* different opiate drugs to *many* plaintiffs, who seek *many* types of damage. For example, opioid cases include non-marketing theories of liability against Distributors and Pharmacies, and many categories of injury that were not at issue in *Neurontin*. Ultimately, due to the more complex nature of the MDL cases, the causation analysis accepted by the First Circuit in *Neurontin* may have no application in opioid litigation.

²¹ West Boca does, however, argue that many states have enacted hospital lien laws, which allow hospitals to claim a portion of a legal award that an uninsured patient might receive for their accident if West Boca attaches the lien within a specified time period. Doc. #: 385 at ¶61. If anything, this heightens the Court's concern that allowing West

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Boca to pursue the first category of damages would lead to double recovery against the Defendants.

²² The Ninth Circuit, in [Washington Public](#), in the factually-distinct context of tobacco litigation, acknowledges the difference between third-party payors and healthcare providers, but concludes it is immaterial. [241 F.3d at 702](#) ("The fact that Plaintiff Districts are health care providers rather than third party health care payers like the union trusts in *Oregon Laborers* is immaterial for purposes of RICO and antitrust standing."). The Third Circuit, in [Allegeny](#), does not even draw the distinction. [228 F.3d at 435](#) ("Plaintiffs raise antitrust and RICO claims that are essentially identical to those the union funds raised in Steamfitters. Therefore, Steamfitters controls.").

²³ Because of the overlap between proximate cause and standing with respect to RICO, the second and third [Holmes](#) factors are addressed in Section IV.B below.

²⁴ Interestingly, it is Defendants who assert that those patients cannot, in fact, seek compensation for their medical expenses and thus vindicate the law as private attorneys general in the interest of deterring injurious conduct. See, e.g., Doc. #: 684-1 at 1 ("[T]hese victims brought claims against the prescription-opioid manufacturers...seeking recovery of personal-injury damages. As far as Distributors are aware, those claims all failed.").

²⁵ See Doc. #: 961-1 at 5.

²⁶ See Doc. #: 961-1 at 4; Doc. #: 684-1 at 11-12.

²⁷ See Doc. #: 961-1 at 7-8; Doc. #: 684-1 at 13.

²⁸ See Doc. #: 961-1 at 5; Doc. #: 684-1 at 10; Doc. #: 686-1 at 3-4. Federal [Rule 9\(b\)](#) is also analyzed in section VI.C below regarding West Boca's FDUTPA claims.

²⁹ The R&R of the Magistrate Judge with respect to the analysis of these sections was adopted by the Court. See Doc. #: 1203.

³⁰ It is not clear from West Boca's complaint or from briefing by the parties whether West Boca's RICO conspiracy claim under [18 U.S.C. § 1962\(d\)](#) is premised solely upon its [§ 1962\(a\)](#) claim, or whether West Boca also intended to allege a conspiracy to commit a substantive violation of [§ 1962\(c\)](#). By the express language of paragraph 893 of the Complaint, West Boca's second cause of action appears to be premised on the [§ 1962\(a\)](#) claim alone, which as discussed below, must be dismissed. Doc. #: 385 at ¶893 ("In violation of [Section 1962\(d\)](#) of RICO, [18 U.S.C. § 1962\(d\)](#), Defendants, with full knowledge and purpose, conspired to violate [Section 1962\(a\)](#) of RICO."). However, given that (1) all parties briefed the issue as though the conspiracy claim applied to both [§§ 1962\(a\)](#) and [\(c\)](#), and (2) there appear to be sufficient allegations within the complaint addressing [§ 1962\(c\)](#) to support a claim for conspiracy to violate that section, the Court assumes West Boca's conspiracy claim is premised upon both [§ 1962\(a\)](#) and [\(c\)](#). See, e.g., Doc. #: 385 at ¶773.

³¹ See, e.g., Doc. #: 385 at ¶155 (noting the defendants are being sued "to the extent that they are engaged in the manufacture, promotion, distribution, sale **and/or dispensing** of opioids") (emphasis added); Doc. #: 385 at ¶¶663-717 (describing in detail that the National Retail Pharmacies "business includes the distribution **and dispensing** of prescription opioids.").

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³² See *Ideal Steel Supply Corp. v. Anza*, 652 F.3d 310, 322 (2d Cir.2011) (reversing dismissal of § 1962(a) claim upon conclusion that defendant, Anza, defrauded the State of New York (a prior victim) out of tax revenue and subsequently invested the ill-gotten racketeering income into a new enterprise, Easton Corporation, in order to purchase property for a competing store that directly injured plaintiff, Ideal Steel).

³³ See *Vemco*, 23 F.3d at 131 (distinguishing *Newmyer v. Philatelic Leasing, Ltd.*, 888 F.2d 385 (6th Cir.1989)). In *Newmyer*, the Sixth Circuit reversed dismissal of plaintiffs' § 1962(a) claim where “ *Newmyer* plaintiffs could have been injured by the investment itself if the investment plan into which they put their money (i.e., the enterprise) was itself funded with monies from **prior** racketeering against **prior** victims” concluding that “an injury resulting from the investment of racketeering proceeds itself was possible.” *Id.* (emphasis added).

³⁴ West Boca attempts to rely on *Busby v. Crown Supply, Inc.*, 896 F.2d 833, 837 (4th Cir. 1990), to support its assertion that it need not plead a distinct investment injury to bring a claim under § 1962(a). *Busby* cannot help West Boca. The Fourth Circuit is one of the few circuits not following the majority rule, and this Court is bound to follow controlling Sixth Circuit precedent. See *Vemco*, 23 F.3d at 132.

³⁵ Defendants also assert West Boca has not sufficiently alleged the Defendants proximately caused the alleged injuries. Causation is addressed in multiple locations throughout this opinion and the Court found it was alleged sufficiently in each instance. See, e.g., Sections III. IV.A; and VI.C.2. For the same reasons, it is alleged sufficiently here.

³⁶ West Boca refers the Court to *Broward County's Opposition Response to the Defendants' Motions to Dismiss*. Doc. #: 703 at 17-18. Broward County cites *Estep*.

³⁷ Pharmacy Defendants give short shrift to their own motion to dismiss West Boca's public nuisance claim. The entirety of their briefing on the issue consists of the following sentence: “The Moving Defendants' brief in *Broward County* explains why Florida law does not allow Plaintiff's nuisance claim. See Moving Defs. Broward County Br. 9-10.” The Pharmacies' *Broward County* brief subsequently incorporates the *Summit County* brief by reference. See Doc. #: 582-1 at 9. Overlooking the differences in types of plaintiffs and the law of the different states at issue in these cases, the Court can only assume that the Pharmacies accept the Court's analysis in *Summit County* as applicable to its motion to dismiss West Boca's claims.

³⁸ This conclusion is on all fours with the Court's analysis of the FDUTPA safe harbor provision in Section VI.C.a below.

³⁹ Rule 9 requires that “[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b).

⁴⁰ For instance, Manufacturer Defendants fail to address the myriad factual allegations set forth by Plaintiff regarding false and misleading statements made in marketing the use of opioids for indications not approved. See Doc. #: 806 at 77-78.

⁴¹ As it relates to reporting requirements, Pharmacy Defendants argue that Plaintiff is asking the Court to “read FDUTPA to impose a duty on every business in Florida to inform all government entities of noncompliance with any regulation ... even when the regulation creates no duty to that government entity **and no consumer has been misled.**” (Emphasis added.) Of course, that is not what Plaintiff actually argues.

⁴² Distributor Defendants also argue these CSA allegations do not meet the Rule 9(b) heightened pleading

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requirement, see Doc. #: 684 at 24, but for the reasons discussed above, the Court finds Plaintiff's allegations are sufficient under Rule 9(b).

⁴³ "FDCA" is the Florida Drug and Cosmetic Act, Florida Statutes, Title XXXIII, Chapter 499, *et seq.*

⁴⁴ Although the Court declines to decide whether violations of the CSA constitute predicate acts under the FDUTPA, the Court makes the following observations. When the CSA was amended in 2008 to prohibit the distribution of controlled substances over the internet, the amendment was titled the "Ryan Haight Online Pharmacy Consumer Protection Act of 2008," presumably indicating its consumer protection goals. See 21 U.S.C.A. §§ 829(e)(1),  841(h). Furthermore, this Court has previously ruled on the significance of Defendants' duties under the CSA. In Track One, this Court articulated that Section 1301.74 of the CSA is a regulation promulgated pursuant to Congressional authority and has the full force and effect of law. See Doc. #: 2483 at 15. The Court also observed that one goal of the CSA is to protect the "public interest" by regulating the "manufacture, distribution, and dispensing of controlled substances." 21 U.S.C. §§ 821 and  823. Still further,  Section 1301.74 imposes a legal duty on registrants to design and operate a SOMS, and to inform the DEA of suspicious orders when discovered by the registrants. Doc. #: 2483 at 15. Finally, the Court ruled that, as part of their duty to maintain effective controls against diversion, registrants under the CSA have a duty not to ship suspicious orders. Doc. #: 2483 at 18. That is, the CSA creates a duty not to put a suspicious order into the stream of commerce where the opioids will be used **by consumers**, absent due diligence.

⁴⁵ Of course, the Court's determination does not mean Plaintiff will ultimately prevail or that the Court agrees with any or all of the theories advanced by Plaintiff. Rather, the court finds only that Plaintiff has alleged facts necessary to withstand a motion to dismiss and will now have the opportunity to pursue, and the burden to prove, its claims.

⁴⁶ Marketing Defendants also argue Plaintiff's allegations do not meet the heightened pleading requirement of Rule 9(b). Doc. #: 691-1 at 11.

⁴⁷ For example, in paragraph 192, Plaintiff identifies a 2009 patient education publication entitled "*Pain: Opioid Therapy*," funded by Endo and posted online, that omitted the term "addiction" from the list of "common risks" of opioid use. This allegation identifies the document, the source of the statement, the methods used to disseminate the statement, and the date and intended audience of the statement.

⁴⁸ Plaintiff purportedly also brought this claim under "Section 672.11," but there is no such section within the Florida UCC.

⁴⁹ Confusingly, in *Plaintiff's Reply in Support of its Second Notice*, Doc. #: 2705, West Boca states it "had also asserted a claim for breach of implied warranty of **merchantability**, but that claim was withdrawn." Case No. 1:18- op-45530, Doc. #: 62 at n.3 (emphasis added). Although Florida law does recognize a separate claim for breach of implied warranty of merchantability, Fla. Stat. § 672.314, the Court is not aware that Plaintiff ever alleged that cause of action. Further, West Boca does not cite to any document purporting to withdraw this (or any) claim. Thus, for clarification, the Court hereby dismisses West Boca's claim for Breach of Implied Warranty of Fitness For a Particular Purpose **and**, to the extent it was ever alleged and not properly withdrawn, dismisses West Boca's Breach of Implied Warranty of Merchantability as well.

⁵⁰ Defendants also challenge proximate causation generally, and those challenges are addressed elsewhere in this opinion.

⁵¹ Distributor Defendants assert they did not breach any duty of care. Breach is addressed in the Negligent Distribution

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section (IX.E.) below.

⁵² Manufacturer Defendants also argue Plaintiff's request for punitive damages based on false advertising and wanton negligence should be stricken because "the Complaint contains only conclusory allegations plainly insufficient to justify such extraordinary relief." Doc. #: 691-1 at 20. This Court will not Strike Plaintiff's request for punitive damages, as motions to strike are disfavored and rarely granted, and the argument raised by Manufacturer Defendants is more appropriately raised at a later phase of this litigation. See, e.g.,  *Berene v. Nationstar Mortg. LLC*, 2016 WL 3944742, at *5 (S.D. Fla. Feb. 5, 2016), rev'd and remanded on other grounds, 686 F.App'x 714 (11th Cir. 2017).

⁵³ For instance, West Boca's reliance on  *Godelia v. Doe 1*, 881 F.3d 1309 (11th Cir. 2018) is misplaced, as that Court upheld plaintiff's claim for negligent misrepresentation, and did not address whether "negligent marketing" claims exist under Florida law.

⁵⁴ Further, Plaintiff indicated that it pled negligent marketing out of "an abundance of caution" and "[w]hether considered (in aggregate) as components of a single negligence count or as separate claims, there is ample authority confirming that allegations of negligence in marketing and distribution are actionable." See Doc. #: 806 at 44. Thus, the Court considers Count IX as essentially pleading in the alternative. Given that Plaintiffs' other negligence claims (Counts VI and VII) survive the motions to dismiss, Count IX is unnecessary and redundant. As noted below, the same is true for Count X.

⁵⁵ See also Doc. #: 1499 at 67-68 (citing to the *Summit County* holding and denying the motion to dismiss plaintiff's unjust enrichment claim, where plaintiff paid for the costs of the harm caused by Defendants' conduct).

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Exhibit 5

In re Pacific Sunwear of Calif., Inc., No. 16-10882,
2016 WL 3564484 (Bankr. D. Del. June 22, 2016)

In re Pacific Sunwear of California, Inc., Not Reported in B.R. Rptr. (2016)

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2016 WL 3564484

United States Bankruptcy Court, D. Delaware.

IN RE: PACIFIC SUNWEAR OF CALIFORNIA,
INC., a California corporation, et al.¹, Debtors.

Case No. 16-10882 (LSS) (Jointly Administered)

Signed June 22, 2016

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MEMORANDUM ON CLASS CERTIFICATION

LAURIE SELBER SILVERSTEIN, UNITED STATES
BANKRUPTCY JUDGE

*1 Before me is the Motion of the Class and PAGA Claimants for Leave to File Class Proof of Claim ("Motion").² By the Motion, Mr. Charles Pfeiffer and Ms. Tamaree Beeney seek permission to file proofs of claim in a representative capacity. Debtors filed their opposition,³ and movants filed a reply.⁴ I heard argument on June 8 and, with the agreement of the parties, accepted into evidence all of the documents attached to the filings. For the following reasons, and to the extent necessary, I will grant the Motion.

Background

In 2011, two lawsuits were filed in California state court

against PacSun entities alleging violations of California labor laws relating to wages and hours. In January 2011, Mr. Pfeiffer filed an action under the California Labor Code Private Attorneys General Act of 2004 (the "PAGA").⁵ In May 2011, Ms. Beeney filed a lawsuit that included a putative class action as well as claims pursuant to the PAGA. These two lawsuits were coordinated as a California Judicial Council Coordinated Proceeding⁶ with a third, and similar lawsuit, previously brought by a Ms. She She Strawder.

While the Strawder class action was previously denied class certification, on February 26, 2016, two of the counts in the Beeney class action were granted class certification. After accepting both factual and expert testimony and hearing oral argument, Judge Elihu M. Berle made detailed findings in a bench ruling, and entered an order granting certification as follows:

Class: All hourly, non-exempt employees of PacSun working in retail locations in the State of California from March 18, 2007 through the date the certification Order is entered, concerning Plaintiff's claims for:

- a) failing to authorize and permit employees to take duty-free rest breaks every four hours or major fraction thereof and to compensate employees therefor; and
- b) requiring employees to undergo security checks and perform closing duties off-the-clock without compensation.

The certification order was entered on February 26, 2016.⁷ Judge Berle did not certify the proposed unpaid accrued vacation pay subclass, the business expense subclass, or the meal period subclass.

In certifying the class, Judge Berle specifically found, among other things, that Ms. Beeney's claims were typical of the rest break and off-the-clock claims of unnamed class members, that common questions of law and fact predominate over individual questions, and that class treatment is superior because the "potential recovery per class member will likely be far less than the fixed costs of litigating an individual action."⁸ Though it does not appear in the order, Judge Berle indicated from the bench that his ruling was without prejudice to decertifying the class as Ms. Beeney had yet to present a detailed management plan and demonstrate the validity of the statistical sample, including whether her statistical

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approach has appropriate validity in this case.⁹

*2 The PacSun bankruptcy cases were filed on April 7, 2016. On that same day, the Debtors filed a plan of reorganization and accompanying disclosure statement. A hearing on the disclosure statement is currently scheduled for June 27, 2016. By motion, the Debtors requested (and ultimately received) approval of a general bar date of June 13, 2016 (“Bar Date”). Notwithstanding Judge Berle’s certification of the Beeney class only two months prior to the filing of the petition, the Debtors did not serve the members of the certified class with notice of the Bar Date. Rather, “informed” by Judge Gropper’s decision in *In re Northwest Airlines Corp.*,¹⁰ the Debtors unilaterally chose to limit notice of the Bar Date to employees who worked for PacSun in the two years prior to the filing of the petition.¹¹

The Parties’ Positions

By the Motion, Mr. Pfeiffer and Ms. Beeney ask that I bless their filing of representative proofs of claim on behalf of their respective constituents. They argue that permitting them to file representative claims merely maintains the status quo, which is warranted as: (i) Debtors failed to notice the class claimants of their right to file claims in the bankruptcy case; (ii) the Beeney class was certified after years of arduous litigation and four failed mediations; (iii) the PAGA claims—brought by both Mr. Pfeiffer and Ms. Beeney—need not be certified in order for individuals to act in a representative capacity; and (iv) Mr. Pfeiffer and Ms. Beeney are appropriate representatives.

The Debtors argue that class certification is inappropriate on multiple grounds. First, the Debtors argue that the “Third Circuit definitively rejected the importation of class action principles into bankruptcy cases” in its 1973 decision *SEC v. Aberdeen Securities Co.*¹² Second, the Debtors argue that the movants do not cite any case permitting a PAGA claimant to file a representative claim in bankruptcy, and this court should not be the first to do so. Third, the Debtors argue that the Motion is a collateral attack on the Bar Date order and that Ms. Beeney and Mr. Pfeiffer were obligated to object to that motion, or stay forever silent.¹³ Fourth, the Debtors argue that, to the extent class claims are allowed, I should exercise my discretion not to permit a class filing in this case. Finally, the Debtors argue that Ms. Beeney and Mr. Pfeiffer

cannot satisfy the requisites of Bankruptcy Rule 7023.

Analysis

I. Mr. Pfeiffer Does Not Need Permission to File His PAGA Claim

Section 501 of the Bankruptcy Code provides that a creditor may file a proof of claim. The proof of claim may be executed by the creditor or the creditor’s authorized agent.¹⁴ Whether a party is an authorized agent of a creditor is a matter of applicable non-bankruptcy law.¹⁵ And, agency may be conferred by statute.¹⁶

*3 Turning to the statute at issue, the PAGA explicitly provides, in pertinent part:

Notwithstanding any other provision of law, any provision of this code that provides for a civil penalty to be assessed and collected by the Labor and Workforce Development Agency or any of its departments, divisions, commissions, boards, agencies, or employees, for a violation of this code, may, as an alternative, be recovered through a civil action brought by an aggrieved employee on behalf of himself or herself and other current or former employees pursuant to the procedures specified in Section 2699.3.

* * *

For purposes of this part, “aggrieved employee” means any person who was employed by the alleged violator and against whom one or more of the alleged violations was committed.¹⁷

On its face, therefore, the PAGA deputizes an aggrieved employee to bring claims on behalf of the State of California against an employer for violations of the California Labor Code as long as certain procedures are met.¹⁸ As such, the aggrieved employee is an agent of the State of California. But, I need not rely only on a straightforward reading of the statute to arrive at this conclusion as the Supreme Court of California has recently issued two opinions describing the nature of this statute.

In *Iskanian v. CLS Transportation Los Angeles, LLC*¹⁹ and *Arias v. Superior Court of San Joaquin County*,²⁰ the

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California Supreme Court interpreted the PAGA in two contexts: whether an employee must comply with class action requirements to bring an action under the PAGA, and whether a waiver of an employee's right to representative action under the PAGA violated public policy and/or was preempted by the Federal Arbitration Act. In *Arias*, the California Supreme Court held that PAGA representatives were not required to comply with class action requirements. And, in *Iskanian*, the California Supreme Court held that, unlike class action lawsuits, a waiver of an employee's right to representative action under the PAGA violated California public policy and was not preempted by the Federal Arbitration Act. Answering these questions required the California Supreme Court to examine both the history and purpose of the PAGA, an analysis which similarly answers the questions before me.

Specifically, the California Supreme Court opined:

A PAGA representative action is therefore a type of *qui tam* action. ‘Traditionally, the requirements for enforcement by a citizen in a *qui tam* action have been: (1) that the statute exacts a penalty; (2) that part of the penalty be paid to the informer; and (3) that, in some way, the informer be authorized to bring suit to recover the penalty.’ The PAGA conforms to these traditional criteria, except that a portion of the penalty goes not only to the citizen bringing the suit but to all employees affected by the Labor Code violation. The government entity on whose behalf the plaintiff files suit is always the real party in interest in the suit.²¹

*4 Contrasting lawsuits under the PAGA to private actions, the California Supreme Court further explained that:

(1) “Representative actions under the PAGA, unlike class action suits for damages, do not displace the bilateral arbitration of private disputes between employers and employees over their respective rights and obligations toward each other.”²²

(2) “[T]he Legislature’s purpose in enacting the PAGA was to augment the limited enforcement capability of the Labor and Workforce Development Agency by empowering employees to enforce the Labor Code as representatives of the Agency.”²³

(3) “[A] PAGA litigant’s status as ‘the proxy or agent’ of the state is not merely semantic; it reflects a PAGA litigant’s substantive role in enforcing our labor laws on behalf of state law enforcement agencies.”²⁴

Because the PAGA authorizes Mr. Pfeiffer to bring suit

under California labor laws as a proxy for or an agent of the State of California, and because he has met the statutory requisites, Mr. Pfeiffer may file a proof of claim based on those same claims. Court permission is not required. Naturally, Ms. Beeney may file her PAGA claims as well.

II. The Class Action Proof of Claim Will Be Permitted with Respect to Class Members Who Would Hold General Unsecured Claims

A. The Third Circuit Has Not Banned Class Action Proofs of Claim in Bankruptcy Cases

As an initial matter, I reject the Debtors’ argument that the Court of Appeals for the Third Circuit has categorically prohibited the filing of class proofs of claim in bankruptcy cases. For this proposition, Debtors cite to *SEC v. Aberdeen Securities Co.*²⁵ In *Aberdeen*, the Third Circuit reviewed the decision of a district court on claims matters in a case under both the Securities Investor Protection Act of 1970 and the Bankruptcy Act. In that decision, the court approved the settlement of one customer claim and remanded with respect to another.

After making those determinations, the Third Circuit affirmed the district court’s refusal to treat each of the claims as part of a class action. The district court had “declined to so order contending that the procedures in the bankruptcy proceeding were adequate to protect the interest of all prospective members of the class.”²⁶ In affirming, the Third Circuit first relied on *In re Penn Central Transportation Company*.²⁷ Its opinion in *Penn Central* is all of three paragraphs and the words “class action” appear nowhere. Rather, the Third Circuit simply affirmed the district court’s discretion in refusing a request by stockholders of Penn Central’s parent company to intervene in the railroad’s bankruptcy case. The district court, in rejecting the class action argument, among others, found that intervention by stockholders on a class action theory was inconsistent with the provisions of the Bankruptcy Act, which permitted the formation of a stockholders’ protective committee. Thus, the *Penn Central* decisions address intervention in the context of committee formation; the decisions do not address class proofs of claim.

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*5 Second, and more importantly, *Aberdeen* is not couched in *per se* language. As the *Aberdeen* Court wrote:

All creditors were given notice of the insolvency proceedings, and they were given the opportunity to file claims. A ruling by the Court as to one category of creditors certainly would apply to all in that group. Furthermore, this is not a plenary suit but a liquidation proceeding which should be concluded as expeditiously as possible. We see no indication that a class action designation would have such a result. The petitioners have failed to show that the method they advocated was superior to the procedures being followed by the Bankruptcy Court. The determination made by the District Court on this point is amply supported by the record and well within its discretion.²⁸

Given this language, it is my view that *Aberdeen* does not stand for the principle that class claims are, as a rule, impermissible in bankruptcy cases. Indeed, the above quoted language in many instances echoes the factors courts consider in determining whether to certify a class.

B. I Will Exercise My Discretion and Apply Rule 7023

Having so held, I will join the vast majority of courts holding that whether to permit a class action is a matter of discretion.²⁹ In exercising that discretion, a two-step analysis is performed. First, I must decide whether it is beneficial to apply Bankruptcy Rule 7023, via Bankruptcy Rule 9014(c), to the claims administration process. Second, I must determine whether the requirements of

 [Federal Rule of Civil Procedure 23](#) have been satisfied, such that a class proof of claim may properly be filed.³⁰ As stated in *Motors Liquidation*, “[a]lthough the Bankruptcy Code and Rules give no express guidance for the court’s exercise of this discretion, a pervasive theme is avoiding undue delay in the administration of the case.”³¹ To achieve that result, courts have developed a three-factor framework to help guide the court’s

discretion in determining if Rule 7023 should be extended. Those factors include: (1) whether the class was certified pre-petition; (2) whether the members of the putative class received notice of the bar date; and (3) whether class certification will adversely affect the administration of the estate.³² I will refer to these factors as the “*Musicland* factors.”

*6 The first two *Musicland* factors are easily addressed. As already discussed, Judge Berle granted class certification for Ms. Beeney’s rest break and off-the-clock claims for nonexempt employees of PacSun working in stores in California from March 18, 2007 forward. And, despite due process requiring actual notice to known creditors, the Debtors admittedly limited notice of the bar date to employees who worked for the company within the two years preceding the petition date. As such, not all members of the prepetition certified class received sufficient notice. The first two factors therefore conclusively weigh in favor of applying Rule 7023 to the matter *sub judice*.

The third *Musicland* factor—the effect of certification on the bankruptcy—also supports applying Rule 7023 here. Many of the cases cited by the Debtors in opposition to the motion are in factual situations quite different from those here. For example, in *Musicland*, the request for permission to file a class proof of claim was filed after the bar date, approval of the disclosure statement, voting on the plan, and the beginning of the confirmation hearing.³³ In contrast, class certification will not adversely affect the administration of the estate here. As of the filing of the Motion, the bar date had yet to pass, and the claims administration process was in its initial stages, if that. Further, the Debtors were aware of the claims by virtue of the movants’ request for permission to file the claims, the five year history of the litigation between the parties, and Judge Berle’s certification of the class just two months before the bankruptcy case was filed. Hence, and unlike in *Musicland* and the many cases with similar fact patterns, there is neither a laches argument nor a surprise element to this request.

Given this procedural posture, application of Rule 7023 will not hinder the chapter 11 process, but rather will promote efficiency by placing potentially thousands of individual claims before the court in a single class claim with competent counsel representing the interests of the class. The alternative—requiring the traditional claims administration process to play out—would likely result in one or more omnibus objections that would have the same effect of obligating the court to determine the validity of

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perhaps thousands of similar claims at once (if adequate notice had been given), but likely without counsel representing the interests of individual claimants, as the costs of defending against any objection likely would exceed the value of the claims themselves. Moreover, even if I were to deny class certification, I would extend the bar date to allow each claimant that did not receive actual notice to file individual claims, which would only result in greater delay.³⁴ By its recent filing for a supplemental bar date, the Debtors seem to recognize this possibility.

The two cases cited by the Debtors do not persuade me otherwise. *Babineau*³⁵ and *Diabate*³⁶ are two non-bankruptcy cases in which class certification was denied because factual determinations regarding off-the-clock work at the end of shifts or during breaks would swamp any class determinations. Debtors argue that these cases support exercising my discretion to decline application of Rule 7023 because certifying the class will not avoid individualized determinations of claims altogether. But, a careful review of these cases actually supports granting the Motion. As explained by the *Diabate* Court, in both of these cases the court determined that there could be no common proof of *liability*. Further, the *Diabate* Court specifically distinguished its case (requiring individualized determinations) from cases, such as this one, “involving class wage claims where *all* employees in the putative class were subject to employer policies *requiring* them to work off-the-clock prior to and/or after their scheduled shifts.”³⁷ Indeed, class actions challenging companywide policies are frequently certified.³⁸

*7 A final consideration that weighs heavily in favor of applying Rule 7023 to this case is the very existence of the PAGA claims. As I have already found, Mr. Pfeiffer does not need permission to file his PAGA proof of claim, and thus I will need to resolve his claim if it is not settled. A review of his PAGA complaint shows that Mr. Pfeiffer alleges the very same claims certified by Judge Berle: off-the-clock work related to required security checks prior to leaving a PacSun store and violation of California’s rest period requirements. It will therefore be necessary to address these claims regardless of whether the class action proof of claim is permitted. Accordingly, I will exercise my discretion to apply Rule 7023 to these proceedings.

III. Rule 23³⁹ is Only Partially Satisfied

In order to certify a class claim, the claimant must satisfy the four elements of  Rule 23(a) as well as one of the subsections of  Rule 23(b).⁴⁰ The party seeking to certify the class bears the burden to establish each element.⁴¹ Most cases I have reviewed do not discuss what evidence, if any, must be produced to meet that burden.⁴² Here, I need not determine the extent of the evidentiary basis needed to support a  Rule 23 motion as the arguments raised by the Debtors do not implicate disputed factual issues.

Debtors argue that Ms. Beeney has failed to carry her burden under  Rule 23 for three reasons: (i) she “lacks standing” to seek class certification for the administrative and priority claims she seeks to pursue in a representative capacity; (ii) she cannot meet the requirements of  Rule 23 as to those claims that Judge Berle declined to certify for class treatment; and (iii) she has not demonstrated that a class action is superior to the traditional bankruptcy claims allowance process.⁴³ In their reply to the Debtors’ objection, the movants clarified that as to Ms. Beeney’s lawsuit, they are only seeking to file class proofs of claim for the two claims Judge Berle certified; accordingly that objection is moot. I will address the other two arguments in the context of my discussion, below.

A. Rule 23(a) Is Satisfied as to Numerosity, Commonality, and Typicality with Respect to All Unnamed Class Members

 Rule 23(a) requires a showing of: (i) numerosity; (ii) commonality; (iii) typicality; and (iv) adequacy of representation.⁴⁴ The Debtors have not challenged numerosity, nor should they. While the numbers in the submissions differ, the class appears to be in excess of 20,000 members. Whether the Debtors challenge commonality, typicality, or adequacy of representation is hard to discern because their submission mashes the concepts together under their “lack of standing” argument. Accordingly, I will go through these separate concepts in order.

Commonality requires the court to determine whether there are “questions of law or fact common to the class.”⁴⁵ The “threshold of commonality is not high.”⁴⁶ And,

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“[b]ecause this requirement may be satisfied by one common issue, it is easily met.”⁴⁷ Further, factual differences among the claims of the putative class are not fatal to certification.⁴⁸ Rather, “what matters to class certification ... [is] the capacity of a classwide proceeding to generate common answers apt to drive the resolution of the litigation.”⁴⁹ Here, Ms. Beeney asserts that all members of the class were subject to companywide policies related to breaks and off-the-clock security checks that violated California law resulting in monetary damages to each class member. This allegation meets the requirement that there be at least one issue common to all class members. Accordingly, the commonality factor is met.

*8 The typicality requirement of subsection (a)(3) is designed to ensure that the interests of the unnamed class members will be adequately protected by the named class members.⁵⁰ The question to answer is whether “the named plaintiff’s individual circumstances are markedly different or ... the legal theory upon which the claims are based differs from that upon which the claims of other class members will perforce be based.”⁵¹ Again, factual differences between the claimant and the unnamed class members does not defeat typicality.⁵² Ms. Beeney’s claims, and in particular, the legal theory on which the claims are based—that companywide practices violate California labor laws—are not only typical of the claims of the unnamed class members, they are identical to their claims. This satisfies the typicality requirement.

B.  Rule 23(a) Is Satisfied with Respect to Adequacy of Representation for Unnamed Class Members Who Would Hold General Unsecured Claims

 Rule 23(a)(4) requires that “the representative parties will fairly and adequately protect the interests of the class.”⁵³ The Third Circuit has recently addressed the adequacy requirement, stating that it “has two components: (1) concerning the experience and performance of class counsel; and (2) concerning the interests and incentives of the representative plaintiffs.”⁵⁴ Debtors have not challenged the experience and performance of class counsel, and, thus, I find this requirement to be satisfied.

The Debtors’ lack of standing argument appears to go to

the second component of adequate representation. They argue that Ms. Beeney’s interests “actively conflict with individuals with wage-and-hour claims entitled to wage priority or administrative claims.”⁵⁵ The Debtors further argue that as a general unsecured creditor, Ms. Beeney “would personally and pecuniarily benefit from minimizing the hundred-cent claims of priority and administrative claimants to enhance the possibility of confirmation, which is the only way in which any funds will be available to general unsecured creditors.”⁵⁶ This argument has more heft.

The “linchpin of the adequacy requirement is the alignment of interests and incentives between the representative plaintiffs and the rest of the class.”⁵⁷ Certain intra-class conflicts may cause a divergence between the interests of the proposed class representative and the unnamed class members rendering the representative plaintiff inadequate.⁵⁸ Not all intra-class conflicts, however, will doom the adequacy requirement; the conflict must be “fundamental” to violate Rule 24(a)(4).⁵⁹ Various circumstances can create a fundamental conflict, including a conflict concerning “the allocation of remedies amongst class members with competing interests.”⁶⁰ The facts and holding of *Dewey* are very instructive here.

Dewey came to the district court for decision as many class actions do: by the filing of two class action complaints, the consolidation of the class actions and, a multi-year discovery period. Thereafter, a joint motion was filed seeking preliminary approval of a settlement, preliminary certification of the class, and appointment of class counsel. In short, the *Dewey* plaintiffs alleged that certain models of Volkswagen and Audi automobiles had defectively designed sunroofs allowing water to leak into the vehicle in certain circumstances. The settlement placed vehicles in one of two groups—the “reimbursement group” or the “residual group”—based on make, model, year and Vehicle Identification Number. As relevant here, the settlement created an \$8 million reimbursement fund to reimburse class members for certain repairs. The reimbursement fund was made available first to members of the reimbursement group. If, and only if, funds remained after payment to members in the reimbursement group, members of the residual group would have access to the \$8 million fund. All of the representative plaintiffs were members of the reimbursement group. After a fairness hearing at which multiple objections were lodged, the district court approved both the class certification and the settlement. In so finding, the district court overruled objections related

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to intra-class conflicts finding that the divisions between the classes were based on objective criteria.

***9** On appeal, the Third Circuit reversed. The court found both that there was an intra-class conflict, and that the conflict was fundamental. The intra-class conflict was evidenced by the structure of the settlement, which placed class members in two classes based on model runs, with the class representatives' lawyers drawing the line between the classes. Because each representative plaintiff was in the reimbursement group, they could not adequately represent the class members in the residual group. The court found that each representative plaintiff had an incentive to exclude as many other class members from the reimbursement group as possible, while plaintiffs in the residual group had an incentive to bargain their way into the reimbursement group.⁶¹ The court also rejected the argument that the representative plaintiffs adequately represented the unnamed class members because it was likely that the \$8 million fund was sufficient to cover members in both the reimbursement class and the residual class. The Third Circuit wrote:

The adequacy requirement provides *structural* protections during the process of bargaining for settlement. The fact that the stars aligned and the class members' interests were not actually damaged does not permit representative plaintiffs to bypass structural requirements.⁶²

Because of this fundamental intra-class conflict, the court found that the class certified below failed to satisfy

 Rule 23(a)(4).

There is an important distinction between the *Dewey* scenario and the scenario presented in the Motion here that, at first blush, might lead one to the opposite conclusion in this case (i.e., that  Rule 23(a)(4) is satisfied). Assuming Ms. Beeney is successful in establishing liability, the dividing line among the various class members—that is, which class members will have a general unsecured claim, a priority claim or an administrative claim—is determined by the Bankruptcy Code, not Ms. Beeney. Ms. Beeney and her lawyers would have no discretion to place members in one class or another. Nonetheless, the structural problem identified by the *Dewey* Court is still present. It is not possible at this time to predict how the litigation, or any settlement, might

unfold. Ms. Beeney, who can only be a member of the general unsecured class,⁶³ has an incentive to favor general unsecured creditors over creditors in other classes. Thus, like in *Dewey*, Ms. Beeney cannot adequately represent all unnamed class members, some of whom will have administrative and/or priority claims if liability is proven. Accordingly,  Rule 23(a)(4), which provides structural protection during the process of bargaining for settlement, is not met with respect to those unnamed class members who are not in the general unsecured creditor class.⁶⁴ On the other hand,  Rule 23(a)(4) is met with respect to those unnamed class members who would hold general unsecured claims.

B.  Rule 23(b) is Satisfied with Respect to all Unnamed Class Members

 Rule 23(b) provides in pertinent part:

A class action may be maintained if  Rule 23(a) is satisfied and if:

(3) the court finds that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.⁶⁵

The requirement that questions of law or fact predominate “ensure[s] that the class is sufficiently cohesive to warrant adjudication by representation.”⁶⁶ This analysis is more strenuous than the commonality test of  Rule 23(a)(2).⁶⁷ Important to the analysis in this case, “it has been commonly recognized that the necessity for calculation of damages on an individual basis should not preclude class determination when the common issues which determine liability predominate.”⁶⁸

***10** Debtors do not seriously contend that common questions of law do not exist in this case. Rather, at another point in their brief, they argue that the class action is only the starting point and that “[i]ndividualized determinations—such as the number of hours worked and number of breaks missed—will be required to determine

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the amount each putative class member is entitled to receive in any distribution.”⁶⁹ That argument was not persuasive previously, and is not with respect to this factor either. While the Debtors may be correct that there will be a need for individualized determinations with respect to damages,⁷⁰ the issues as to liability are whether the Debtors’ companywide policies violate California law. This issue of law forms the basis for the claims of all class members; indeed, if Debtors are correct that they have not violated California law, no class member will have a claim. Accordingly, common questions predominate.

Further, in this instance, a class action is superior to “other available methods for fairly and efficiently adjudicating the controversy.” This requirement looks at the management of the class action.⁷¹ Judge Walrath’s analysis in *United Companies* is directly on point here. First, as in *United Companies*, it is probably the case that most unnamed class members do not know of their rights under California law, so it is unlikely they would file claims even if they received proper notice. And, as came out at argument, the unnamed class members have not previously received notice of the state court certification. Second, as the Debtors admitted, and as Judge Berle found, the recovery of each class member (regardless of priority) is likely to be relatively small, rendering prosecution of such claims cost-prohibitive. While it is true that the cost of filing a claim is *de minimis*, the cost of defending the inevitable objection is not. Finally, I agree with Judge Walrath, that the filing of a class claim is similar procedurally to a debtor’s use of an omnibus objection, which has become ubiquitous in this court. Omnibus objections present (or should present) common issues that are amenable to global resolution. In this instance, I have no doubt that any individual claims filed on the basis of the class action would be met with an omnibus objection. Thus, to permit the filing of a class claim will streamline the resolution of the legal issues. As with omnibus objections, objections to individual claims can be subsequently resolved.⁷² For all of these reasons, I find the filing of a class proof of claim to be a superior method to resolve these claims.

Conclusion

For the reasons set forth above, I will grant the Motion in part and deny it in part. First, I conclude that I need not pre-approve any claims brought under the PAGA. Second, I certify the following:

Class: All hourly, non-exempt employees of PacSun working in retail locations in the State of California from March 18, 2007 through the 181st day prior to the filing of the bankruptcy petition concerning Ms. Beeney’s claims for:

- a) failing to authorize and permit employees to take duty-free rest breaks every four hours or major fraction thereof and to compensate employees therefor; and
- b) requiring employees to undergo security checks and perform closing duties off-the-clock without compensation.

Having done so, I observe that I do have concerns that the cost of litigating/resolving these claims not eat up any recoveries that would go to these creditors—if in fact they have valid claims—or other creditors. Accordingly, I encourage the parties to discuss both appropriate procedures for determining these claims in an efficient manner, at the least amount of cost to the estate and the claimants, and a resolution of these claims. An order will enter.

All Citations

Not Reported in B.R. Rptr., 2016 WL 3564484, 75 Collier Bankr.Cas.2d 1935, 62 Bankr.Ct.Dec. 212

Footnotes

¹ The Debtors and the last four digits of their respective federal taxpayer identification numbers are as follows: Pacific Sunwear of California, Inc. (9463–CA); Miraloma Borrower Corporation (0381–DE); and Pacific Sunwear Stores Corp. (5792–CA). The Debtors’ address is 3450 East Miraloma Avenue, Anaheim, CA 92806.

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² Docket No. 378.

³ Debtors' Opposition to Motion of Class and PAGA Claimants for Leave to File Class Proof of Claim ("Objection"). Docket No. 414.

⁴ Reply of the Class and PAGA Claimants in Support of Their Motion for Leave to File Class and PAGA Proof of Claim ("Reply"). Docket No. 432.

⁵ Cal. Lab.Code §§ 2698– 2699.5.

⁶ *In re Pacific Sunwear Consolidated Cases*, Case No. JCCP4671, Superior Court of the State of California for the County of Los Angeles, Department 323.

⁷ Reply Ex. B.

⁸ Order Granting in Part and Denying in Part Plaintiff Tamaree Beeney's Motion for Class Certification at 2 (Ex. C to Objection).

⁹ Class Certification Hr'g Tr. at 45, Nov. 24, 2015 (Ex. D to Objection).

¹⁰  2007 WL 2815917 (Bankr.S.D.N.Y. Sept. 26, 2007).

¹¹ Objection ¶ 19 n.8.

¹²  480 F.2d 1121 (3d Cir.1973).

¹³ This argument is rejected out of hand. It is a debtor's burden to provide proper notice to its known creditors. To the extent that a debtor seeks a ruling on the sufficiency of notice to particular creditors, the motion to establish the bar date should specifically reference that issue, which did not happen in this case. It may also behoove a debtor to specifically raise that issue with the judge in court. Moreover, Judge Gropper's decision in *Northwest Airlines* does not establish a generic or global standard for noticing members of an employee class action as the Debtors' position suggests. Rather, *Northwest Airlines* addressed whether notice issues required class certification, not whether notice was proper to any particular member of the class. Further, the decision was specifically limited to "the circumstances of this case."  2007 WL 2815917, at *4. I also note that in *Northwest Airlines* the court presiding over the litigation had **denied** class certification prepetition.

¹⁴ Federal Rule of Bankruptcy Procedure 3001(b).

¹⁵  *In re Griffin Trading Co.*, 270 B.R. 883 (Bankr.N.D.Ill.2001) (applying law of the United Kingdom to determine whether Joint Liquidators were "agents" as contemplated by Rule 3001(b)); *In re Thalmann*, 469 B.R. 677 (Bankr.S.D.Tex.2012) (state law determines whether entity is authorized agent of creditor).

¹⁶ 9 Collier on Bankruptcy ¶ 3001.06 (Alan Resnick & Henry J. Sommer eds., 16th ed.). Cf.  *Nathanson v. NLRB*, 344 U.S. 25, 27 (1952) (National Labor Relations Board is a creditor within the meaning of the Bankruptcy Act with respect to back pay awards, as it is the public agent chosen by Congress to enforce the National Labor Relations Act).

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¹⁷ PAGA § 2699.

¹⁸ The requisite procedures have been met here. See Reply Exs. A & B.

¹⁹ 327 P.3d 129 (Cal.2014).

²⁰ 209 P.3d 923 (Cal.2009).

²¹ *Iskanian*, 327 P.3d at 148 (citations omitted).

²² *Id.* at 152.

²³ *Id.* at 149.

²⁴ *Id.* at 316 (emphasis added) (citing *Arias*, 209 P.3d at 933).

²⁵ 480 F.2d 1121 (3d Cir.1973).

²⁶ *Id.* at 1128.

²⁷ 328 F.Supp. 1273 (E.D.Pa.1971), *aff'd*, 455 F.2d 976 (3d Cir.1972) (*per curiam*).

²⁸ *Aberdeen*, 480 F.2d at 1128.

²⁹ See, e.g., *Reid v. White Motor Corp.*, 886 F.2d 1462, 1469 (6th Cir.1989); *In re Charter Co.*, 876 F.2d 866, 873 (11th Cir.1989); *In re Am. Reserve Corp.*, 840 F.2d 487, 493 (7th Cir.1988); *Zenith Labs., Inc. v. Sinay (In re Zenith Labs., Inc.)*, 104 B.R. 659, 662 n.2 (D.N.J.1989); *Iles v. LTV Aerospace & Defense Co. (In re Chateaugay Corp.)*, 104 B.R. 626, 629 (S.D.N.Y.1989); *In re First Interregional Equity Corp.*, 227 B.R. 358, 366 (Bankr.D.N.J.1998); *In re Woodward & Lothrop Holdings, Inc.*, 205 B.R. 365, 370 (Bankr.S.D.N.Y.1997); *In re Sacred Heart Hosp. of Norristown*, 177 B.R. 16, 22 (Bankr.E.D.Pa.1995). But see *Kahler v. FIRSTPLUS Fin., Inc. (In re FIRSTPLUS Fin., Inc.)*, 248 B.R. 60, 72 (Bankr.N.D.Tex.2000) (class proof of claim is improper in the bankruptcy context).

³⁰ *In re MF Global Inc.*, 512 B.R. 757, 763 (Bankr.S.D.N.Y.2014); *In re Motors Liquidation Co.*, 447 B.R. 150, 157 (Bankr.S.D.N.Y.2011).

³¹ *Motors Liquidation*, 447 B.R. at 157 (quoting *In re Ephedra Prods. Liab. Litig.*, 329 B.R. 1, 5 (S.D.N.Y.2005)).

³² *In re Musicland Holding Corp.*, 362 B.R. 644, 654–55 (Bankr.S.D.N.Y.2007).

³³ *Musicland*, 362 B.R. at 656.

³⁴ See *MF Global Inc.*, 512 B.R. 757 (Bankr.S.D.N.Y.2014).

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35  *Babineau v. Fed. Express Corp.*, 576 F.3d 1183 (11th Cir.2009).

36  *Diabate v. MV Transp., Inc.*, 2015 WL 4496616 (E.D.Pa. July 20, 2015).

37 *Id.* at *11.

38 *Id.* at *11 (citing  *Bouaphakeo v. Tyson Foods, Inc.*, 765 F.3d 791 (8th Cir.2014) (unpaid donning and doffing of protective equipment), *aff'd and remanded*,  136 S.Ct. 1036 (2016) and  *Keller v. TD Bank, N.A.*, 2014 WL 5591033 (E.D.Pa. Nov. 4, 2014) (employer policy that all retain bank employees work off-the-clock to perform pre-shift or post-shift security procedures when they opened or closed a branch)).

39 Bankruptcy Rule 7023 incorporates  Fed.R.Civ.P. 23.

40 *In re United Cos. Fin. Corp.*, 276 B.R. 368, 372 (Bankr.D.Del.2002).

41 *Id.*

42 See, e.g., *Walling v. Brady*, 1995 WL 447658 (D.Del. July 19, 1995) (citing  *Blackie v. Barrack*, 524 F.2d 891, 901 n.17 (9th Cir.1975)) (for the limited purpose of deciding the class action motion, court considers pleadings and affidavits accurate).

43 The same arguments were made with respect to Mr. Pfeiffer, but as set forth *infra*, Mr. Pfeiffer does not need to meet the class action standards in order to file a claim. His claim is governed by the PAGA, and any argument that Mr. Pfeiffer's claim, as filed, exceeds his authority under the PAGA must be addressed in the claims resolution process.

44  Fed.R.Civ.P. 23(a); *United Cos.*, 276 B.R. at 372.

45  Fed.R.Civ.P. 23(a)(2).

46 *United Cos.*, 276 B.R. at 373 (quoting  *In re Sch. Asbestos Litig.*, 789 F.2d 996, 1010 (3d Cir.1986)).

47 *Walling*, 1995 WL 447658, at *3 (citing  *Baby Neal v. Casey*, 43 F.3d 48, 56 (3d Cir.1994)).

48 *United Cos.*, 276 B.R. at 373 (quoting  *Baby Neal*, 43 F.3d at 56).

49 *Diabate*, 2015 WL 449616, at *9 2015 WL 449616, at *9 (quoting *Wal-Mart Stores, Inc. v. Dukes*, 521 U.S. 338, 350 (2011)).

50 *United Cos.*, 276 B.R. at 373.

51 *Id.* (quoting  *Weiss v. York Hosp.*, 745 F.2d 786, 810 (3d Cir.1984)).

52 *Id.* at 374.

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53  Fed.R.Civ.P. 23(a)(4).

54  *Dewey v. Volkswagen Aktiengesellschaft*, 681 F.3d 170, 181 (3d Cir.2012) (citing  *In re Cnty. Bank of N. Va.*, 418 F.3d 277, 303 (3d Cir.2005)).

55 Objection ¶ 68.

56 *Id.*

57  *Dewey*, 681 F.3d at 183.

58 *Id.* at 184–85.

59 *Id.* at 184.

60 *Id.*

61 *Id.* at 188.

62 *Id.* at 189 n.19.

63 Ms. Beeney worked at PacSun from May 2007 to May 2010, well outside the priority and administrative periods.

64 Also, like in *Dewey*, there may be a way to satisfy  Rule 23(b). See  *Dewey*, 681 F.3d at 189–90.

65  Fed.R.Civ.P. 23(b).

66 *United Cos.*, 276 B.R. at 374–75.

67 *Id.* at 375 (citing  *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 624 (1997)).

68  *Bogosian v. Gulf Oil Corp.*, 561 F.2d 434, 456 (3d Cir.1977); *United Cos.*, 276 B.R. at 376.

69 Objection ¶ 61.

70 But see  *Tyson Foods v. Bouaphakeo*, 136 S.Ct. 1036, 1048 (2016) (“Whether a representative sample may be used to establish classwide liability will depend on the purpose for which the sample is being introduced and on the underlying cause of action ... The fairness and utility of statistical methods ... will depend on facts and circumstances particular to [the case].”).

71 *United Cos.*, 276 B.R. at 376.

72 *United Cos.*, 276 B.R. at 376.

Exhibit 6

In re Spring Ford Indus., No. 02-15015 DWS,
2003 WL 21785960 (Bankr. E.D. Pa. July 25, 2003)

In re Spring Ford Industries, Inc., Not Reported in B.R. (2003)

2003 WL 21785960

KeyCite Yellow Flag - Negative Treatment
Distinguished by [In re DDI Corp.](#), Bankr.S.D.N.Y., February 19, 2004
2003 WL 21785960

Only the Westlaw citation is currently available.
United States Bankruptcy Court,
E.D. Pennsylvania.

In re SPRING FORD INDUSTRIES, INC., a.k.a.
Spring Ford Knitting Company, Inc., Debtor.

No. 02-15015DWS.
|
July 25, 2003.

Attorneys and Law Firms

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[Silvia M. Ferri](#), Philadelphia, PA, for Claimants.

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MEMORANDUM OPINION

[SIGMUND](#), Bankruptcy J.

*1 Before the Court is the Motion of Paula O'Gorman and Sarah Vuotto, Individually and on Behalf of Those Similarly Situated (the "Claimants"), to Enlarge the Time to File a Proof of Claim Nunc Pro Tunc (the "Motion"). For the reasons stated below, I will grant the Motion.

BACKGROUND

The following facts are derived from the court record¹ and/or are uncontested.² On or about December 19, 2001, the Claimants, former employees of the Debtor, filed a

class action suit in the Eastern District of Pennsylvania (the "District Court Case") alleging that the Debtor violated the Worker Adjustment and Retraining Notification Act ("WARN Act"), 29 U.S.C. § 2101, et seq, by failing to give 60-day notice to certain workers affected by a plant closing. Exhibit A to Motion. On April 2, 2002, the Debtor filed a petition under Chapter 11 which operated as an automatic stay of the District Court Case. 11 U.S.C. § 362(a)(1). Debtor notified the Claimants of the filing by faxing the same to Claimants' attorney on April 9, 2002.³ Prior to the litigation stay, a class had not been certified.

The Debtor acknowledges failing to schedule the Claimants as unsecured creditors, but listing the District Court Case on its Statement of Financial Affairs. As such, the Claimants did not receive notice of the bar date, which I set at July 2, 2002 by order dated May 21, 2002. An unliquidated class claim was filed on August 8, 2002.⁴

Some eight months later, on March 25, 2003, the Debtor filed an objection to the Claim on the basis that it was filed after the bar date, it did not specify a claim amount, and the Debtor's records did not show that it owed the Claimants any monies (the "Objection").⁵ On April 10, 2003, presumably in response to the Objection, the Claimants filed the Motion to Enlarge that is before me now.

After the claim was filed and before the Objection was lodged, Debtor filed various plans and disclosure statements, none of which discussed a potential WARN act claim. I confirmed the Fourth Amended Plan on November 26, 2002.

The Claimants assert that not filing a proof of claim despite actual knowledge of the bankruptcy case does not bar their claim. They argue that known creditors without notice of the bar date should be permitted to file an untimely claim under the excusable neglect standard of Bankruptcy Rule 9006(b)(1). They state the delay to filing was minimal, they made a good faith inquiry to obtain a proof of claim, and the Debtor's reorganization case suffered no prejudice because the plan of reorganization was filed and confirmed after the Proof of Claim was filed.

The Debtor concedes that a late filing due to failure to receive actual notice of a bar date could constitute excusable neglect. See Memorandum of Points and

In re Spring Ford Industries, Inc., Not Reported in B.R. (2003)

2003 WL 21785960

Authorities of Spring Ford Industries, Inc. in Opposition to the Motion (“Debtor’s Memo”) at 7. However, it maintains that the Claimants did not act in good faith as they delayed filing their Motion for eight months and until after the plan confirmation to the prejudice of estate. See Debtor’s Response to Motion ¶ 19.

DISCUSSION

I.

*2 The court “shall fix and for cause shown may extend the time within which proofs of claim or interest may be filed.” Fed. R. Bankr.P. 3003(c)(3). Creditors are then entitled to twenty days notice of the time fixed for filing a proof of claim. Fed. R. Bankr.P.2002(a)(7). After the bar date has expired, the court may permit the filing of a claim “where the failure to act was the result of excusable neglect.” Fed. R. Bankr.P. 9006(b).

The United States Supreme Court, in [Pioneer Inv. Serv. Co. v. Brunswick Assocs. Ltd. Partnership](#), 507 U.S. 380, 113 S.Ct. 1489 (1993), explained that excusable neglect requires inquiry into whether the failure to file resulted from neglect and then whether that neglect is excusable. Neglect encompasses both simple, faultless omissions to act and, more commonly, omissions caused

by “carelessness” [Id. at 388, 113 S.Ct. at 1495](#). The determination of whether the neglect is excusable is “at bottom an equitable one, taking account of all relevant circumstances surrounding the party’s omission. These include ... the danger of prejudice to the debtor, the length of the delay and its potential impact on judicial proceedings, the reason for the delay, including whether it was within the reasonable control of the movant, and whether the movant acted in good faith.” [Id. at 395, 113 S.Ct. at 1498](#). See also [Welch & Forbes, Inc. v. Cendant Corp. \(In re Cendant Corp. Prides Litigation\)](#), 233 F.3d 188, 196 (3d Cir.2000) (court shall consider totality of the circumstances). The burden of proof rests with the petitioner claiming excusable neglect to justify the allowance of a late proof of claim. [Jones v. Chemetron Corp.](#), 212 F.3d 199, 205 (3d Cir.2000).

II.

The Claimants’ failure to file a proof of claim before the bar date was a simple, faultless omission and qualifies as “neglect.” [Pioneer](#), 507 U.S. at 388. See also [In re Lashinger](#), 1999 WL 409389 at *2 (Bankr.E.D. Pa. June 15, 1999) (“no question” that failure to timely file constitutes neglect). For the reasons that follow, I also find that the neglect was excusable.

Reason for Delay. The untimely filing resulted from Claimants’ failure to receive actual notice of the bar date, a justification that has been found to support late filing. *Pioneer*, *supra* (unusual form of notice required finding that neglect was excusable); [Elsom v. Woodward & Lothrop](#), 1997 WL 476091 at *2 (E.D.Pa. Aug. 14, 1997) (claimants improperly notified of bar date not bound by it and may file late claims). See also [Greyhound Lines, Inc. v. Rogers \(In re Eagle Bus Mfg., Inc.\)](#), 62 F.3d 730, 735 (5th Cir.1995) (creditor’s claim can be barred for untimeliness only if received reasonable notice) (citation omitted). Where, as here, the absence of notice is a result of Debtor’s omission, the case is even stronger. [Manus Corp. v. NRG Energy, Inc. \(In re O’Brien Environmental Energy, Inc.\)](#), 188 F.3d 116, 128–29 (3d Cir.1999) (neglect excusable due in part to debtor’s failure “to properly alert and notify” creditor to objection to claim).

*3 While it is true that Claimants knew of the bankruptcy case, they had no duty to inquire about the claims bar date. [New York v. New York, N.H. & H.R. Co.](#), 344 U.S. 293, 297, 73 S.Ct. 299, 301 (1953) (“[E]ven creditors who have knowledge of a reorganization have a right to assume that the statutory ‘reasonable notice’ will be given them before their claims are forever barred.”).

See also [Levin v. Maya Construction Co. \(In re Maya Constr. Co.\)](#), 78 F.3d 1395, 1399 (9th Cir.), cert. denied, 519 U.S. 862, 117 S.Ct. 168 (1996) (as creditor’s actual knowledge of bankruptcy proceeding “does not obviate the need for notice” no “duty to investigate and inject himself into the proceedings.”) (citations omitted); [Joseph B. Dahlkemper Co. v. Liberatore \(In re Joseph B. Dahlkemper Co.\)](#), 170 B.R. 853, 861 (Bankr.W.D.Pa.1994) (“The responsibility does not lie with creditors or claimants to search out what is required

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procedurally of them in this regard. The bankruptcy rules provide them with a right to appropriate and effective notice.”).

Here the Claimants were known creditors of the Debtor, having initiated a lawsuit in the District Court on their claims. The Debtor evidenced its awareness of Claimants’ claim by noting the District Court Case on its Schedules and faxing its bankruptcy petition to the Claimants, presumably to secure the “breathing spell” the automatic stay affords with respect to the litigation. Having been notified of the bankruptcy case by Debtor, Claimants had a reasonable expectation that they were on the service list and would receive notices, including the bar date notice. While the Debtor contests the claims asserted by the Claimants, they are still claims under the Bankruptcy Code. 11 U.S.C. § 101(5) (right to payment whether, *inter alia*, reduced to judgment, unliquidated, disputed), and the holders are creditors. 11 U.S.C. § 101(10) entitled to notices under Bankruptcy Rule 2002(a)(7). Yet the Debtor inexplicably did not provide notice of the bar date to the Claimants. Thus, the Claimants had good reason for their delay in filing the claim.

Good Faith. While I find that Claimants could have acted more responsively, I find no basis to conclude that they did not act in good faith. “[B]lamelessness on the part of the movant is no longer the standard of ‘excusable neglect.’” In re Herman’s Sporting Goods, 166 B.R. 581, 584 (Bankr.D.N.J.1994), citing Pioneer, 507 U.S. at 394, 113 S.Ct. at 1498. See also Cendant Corp., 311 F.3d at 302 (“Although Chase’s lack of diligence in following the progress of the Court’s proceedings is far from commendable, it did not amount to a lack of good faith.”). Significantly, the Debtor has not alleged that Claimants acted in bad faith nor has any evidence probative of bad faith been presented. See In re Sacred Heart Hospital of Norristown, 186 B.R. 891, 897 (Bankr.E.D.Pa.1995) (no evidence of conscious or tactical decision to file late claim which might raise issue of bad faith).

*⁴ It is true that the Claimants failed to seek to enlarge the time for filing at the same time as they filed the proof of claim. Had they done so, their good faith would have been manifest. Herman’s, 166 B.R. at 585 (good faith evidenced by diligently making motion to enlarge time promptly after filing late claim). However, there is no evidence that their delayed action was a stratagem or motivated by some improper purpose. “[A] careless

mistake in professional judgment is not bad faith.” In re Pappalardo, 210 B.R. 634, 647 (Bankr.S.D.Fla.1997). See also Sacred Heart, *supra*; In re Earth Rock, Inc., 153 B.R. 61 (Bankr.D.Idaho 1993).

Delay. The Debtor claims prejudice by the late filing in that it will have to try the class action at this late date and the administration of the bankruptcy case will be delayed. I find these contentions hollow in the face of the evidence. There was a class action pending in the District Court when the bankruptcy case was filed. While it was Claimants’ obligation to prosecute their claim by taking some action in this Court to get relief from stay or estimate the claim,⁶ the Debtor was aware of the pendency of the claims and ignored them. If the Debtor is prejudiced, it is partially of its own doing. While the proof of claim was filed but one month late, Debtor waited eight more months to object and bring this matter to a head.⁷ It cannot be heard to complain now that it is prejudiced by being required to try this case after its plan has been confirmed and the estate partially administered. The Third Circuit made the same observation in O’Brien when it recognized that the delay in Debtor’s case would have been decreased had it reacted promptly, stating:

the detrimental impact of this delay is as much due to O’Brien’s strategic decision to not object to or litigate Manus’s claim until the fairly tight time frame between confirmation and the effective date of the Plan. Here, the delay factor in the excusable neglect inquiry should not be held to turn entirely on the urgency created by the debtor’s time line.

188 F.3d at 130. *Id.*

Cf. Eagle Bus, 62 F.3d at 739 (criticizing the debtor for negotiating with the claimants for months after the bar date passed without raising the late claim issue). While I ascribe no similar motivation to Debtor since I have no basis to conclude why it did not seek a more timely resolution of its objection, it is nonetheless appropriate to evaluate its claims of prejudice in light of its own inaction.

More significantly, even though the plan has been confirmed and distributions begun, the relevant time period in consideration is not the delay from the bar date to the present, or even to when the Claimants’ filed their Motion but the delay from the bar date to the filing of the late claim. In In re Orthopedic Bone Screw Products Liability Litigation, 246 F.3d 315, 325 (3d Cir.2001), the

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Third Circuit observed that “consideration of the current effect of the delay on the proceedings would conflict with our holding that the length of the delay should be considered in absolute terms and not by reference to the import of intervening circumstances.” *Id.*, citing  *O'Brien*, 188 F.3d at 130 (actual delay of two months only took on significance because of intervening effectiveness of plan). Here, the delay was minimal, and the filing occurred before any plan of reorganization was proposed.

*5 *Prejudice to the debtor.* Prejudice occurs when allowance of a late claim would injure or damage the debtor.  *O'Brien*, 188 F.3d at 126. Factors to consider in determining whether the debtor would be prejudiced by the late filing may include “the size of the claim with respect to the rest of the estate; whether allowing the late claim would have an adverse impact on the judicial administration of the case; whether the plan was filed or confirmed with knowledge of the existence of the claim; the disruptive effect that the late filing would have on the plan or upon the economic model upon which the plan was based; and whether allowing the claim would open the floodgates to other similar claims.” *Id.*

Thus, prejudice has been found where a claim was filed after plan confirmation and a major portion of assets had been distributed,  *In re Drexel Burnham Lambert Group*, 148 B.R. 1002, 1007 (S.D.N.Y.1993), and where a plan had been formed, negotiated and confirmed, distribution had begun, and the late filed claim was in an amount much greater than anticipated by the debtor. *Alexander's*, 176 B.R. at 722. On the contrary, no prejudice has been found where a liquidating Chapter 11 plan was filed since the late claim merely reduced the percentage each creditor would receive from the total distribution,  *Sacred Heart*, 186 B.R. at 897;  *Orthopedic Bone Screw Products*, 246 F.3d at 323 (plan included a cap on damages, so no impact on debtor); where the plan was negotiated and approved after the debtor had notice of claims and there was no showing by the debtor that the size of the claim was large in relation to the estate,  *In re Eagle Bus*, 62 F.3d at 738; and where a reserve fund was set aside for disputed claims, *In re Wheeling-Pittsburgh Steel Corp.*, 128 B.R. 391, 393 (Bankr.W.D.Pa.1991).

This contested matter is notable by the absence of any evidence that would address prejudice as described in the aforementioned cases. Notably as “Prejudice is not an

imagined or hypothetical harm; a finding of prejudice should be a conclusion based on facts in evidence.”

 *O'Brien*, 188 F.3d at 127. As the Third Circuit cautioned, *Pioneer* requires more detailed analysis of prejudice than whether the plan sets aside money to pay the claim, otherwise, “virtually all late filings would be condemned by this factor.”  *Id.* at 126. The Debtor’s sole contention of prejudice is that it would be required to liquidate the class claim at this late date resulting in a delayed administration of the case. Debtor does not address (and certainly has provided no evidence of) the impact of the claim, if allowed. Neither party attempted to quantify the potential class claim which, arguably, if large enough, could impact anticipated creditor recoveries even though the information of record would indicate to the contrary.⁸ Perhaps that is the reason Debtor does not make that argument in response to the Claimants’ contention that the Debtor is not prejudiced by the late filing because it was able to propose and confirm a reorganization plan subsequent to the filing of the Claimants’ late claim.

*6 Notably the prejudice alleged by the Debtor is not a consequence of the late filing but the timing of this contested matter. However, the claim was filed before the plan, and Debtor had every opportunity to take it into account in formulating the plan’s terms.  *Eagle Bus*, 62 F.3d at 737 (no prejudice as plan negotiated and approved after the debtor had notice of the claims); see  *Alexander's Inc.*, 176 B.R. 715, 722 (Bankr.S.D.N.Y.1995) (expectation of claim is one factor to consider in determining if debtor is prejudiced);  *Herman's*, 166 B.R. at 584 (“Well before the negotiations debtor was fully aware of the existence of movant's claim and of the pending motion to extend the time to file the proof of claim. To the extent that Debtor assumed the court would decide the motion in its favor by excluding the lease rejection claim from negotiations, it did so at its own risk, and would have been a cause of any prejudice that might have occurred.”).

While I do not find Claimants blameless for failing to prosecute their unliquidated claim by either an estimation proceeding or seeking relief from stay to continue the District Court Case, there was no impediment to the Debtor likewise taking the appropriate action to liquidate this claim. In the end, however, neither party argued that the potential size of the claim in relation to the Debtor’s estate would or would not disrupt the distribution of assets. See  *Greyhound*, 62 F.3d at 738 (debtor did not show that size of claims would disrupt distribution).

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Without regard to size of the claim, it is clearly provided for under the Debtor's confirmed plan which contemplates payment on account of disputed, liquidated or contingent claims to be paid when allowed. Thus, if allowed as an unsecured claim, Claimants would participate pro rata in a fund consisting of the proceeds of the liquidated assets. Fourth Amended Plan of Reorganization ¶¶ 3.7, 6.2 (Doc. No. 315). Since the plan is a liquidating plan, the consequence of allowance could be a reduction in the pro rata distribution, a consequence that courts have concluded is not a sufficient basis to bar a late filing as prejudicial.

CONCLUSION

In conclusion, I hold that the Claimants have demonstrated excusable neglect under Rule 9006(b), and therefore I will grant the Claimants' Motion to Enlarge the Time to File a Proof of Claim Nunc Pro Tunc. An Order consistent with this Memorandum Opinion shall be entered.

ORDER

AND NOW, this 25th day of July 2003, upon consideration of the Motion of Paula O'Gorman and Sarah Vuotto, Individually and on Behalf of Those Similarly Situated, to Enlarge the Time to File a Proof of Claim Nunc Pro Tunc (the "Motion"), after notice and hearing and for the reasons stated in the foregoing Memorandum Opinion;

It is hereby ORDERED that:

The Motion to Enlarge the Time to File a Proof of Claim Nunc Pro Tunc is GRANTED.

All Citations

Not Reported in B.R., 2003 WL 21785960

Footnotes

¹ I shall take judicial notice of the docket entries in this case. Fed.R.Evid. 201, incorporated in these proceedings by Fed.R.Bankr.P. 9017. See *Maritime Elec. Co., Inc. v. United Jersey Bank*, 959 F.2d 1194, 1200 n.3 (3d Cir.1991); *Levine v. Egidi*, 1993 WL 69146, at *2 (N.D.Ill.1993); *In re Paolino*, 1991 WL 284107, at *12 n. 19 (Bankr.E.D.Pa.1991); see generally *In re Indian Palms Associates, Ltd.*, 61 F.3d 197 (3d Cir.1995). While a court may not take judicial notice *sua sponte* of facts contained in the debtor's file that are disputed, *In re Augenbaugh*, 125 F.2d 887 (3d Cir.1942), it may take judicial notice of adjudicative facts "not subject to reasonable dispute ... [and] so long as it is not unfair to a party to do so and does not undermine the trial court's factfinding authority." *In re Indian Palms Assoc.*, 61 F.3d 197, 205 (3d Cir.1995) (citing Fed.R.Evid. 201(f) advisory committee note (1972 proposed rules)). Moreover, "factual assertions in pleadings, which have not been superceded by amended pleadings, are judicial admissions against the party that made them. *Larson v.. Gross Bank*. 204 B.R. 500, 502 (W.D.Tex.1996) (statements in schedules). See also *In re Musgrove*, 187 B.R. 808 (Bankr.N.D.Ga.1995) (same); *In re Leonard*, 151 B.R. 639 (Bankr.N.D.N.Y.1992) (same).

² Neither party sought to make an evidentiary record.

³ On July 9, 2002, the District Court entered an order staying the District Court Case.

⁴ As Claimants presented no evidence, the circumstances that gave rise to the filing on August 8th are not of record. *In*

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re F.B.F. Industries, Inc., 1995 WL 691893 *10 n.4 (Bankr.E.D.Pa.1995) (citing  *Braden v. University of Pittsburgh*, 477 F.2d 1, 6 (3d Cir.1977) (statements in brief do not constitute record evidence unless admitted by the opposing party)).

- ⁵ At the request of counsel for the parties, I have continued the hearing on the merits of the Objection pending a determination of whether the time to file the proof of claim may be enlarged. Following the hearing, I allowed the Debtor's counsel to respond to the Claimants' brief. In its response, it raised a new issue, not framed by the Objection but noted at the hearing. It argues that the proof of claim should be disallowed because it is an improper class claim since the class was not certified prior to the bankruptcy case being filed. In their reply, Claimants contend that the issue is not presently before the Court. I expressly took under advisement the question of timeliness, all parties agreeing that it would be a waste of judicial resources to reach the merits of the Objection if the claim was time barred. Had the class action issue been set forth in the Objection and argued at the hearing, I would have likely reached it now but it was not. While Debtor has thoroughly briefed the question and Claimants have responded without waiving their own waiver argument, Claimants' procedural objection is well taken if not exactly practical. Therefore, I will neither rule on the adequacy of the proof of claim as a class claim nor the Claimants' position that Debtor has waived that basis to object. This matter is continued until August 25, 2003 for a merits hearing. Unless Debtor believes its objection to the class nature of the claim is framed by the existing boilerplate form objection, it should take appropriate steps to present the class claim objection through amendment to its Objection. At such time, Claimants will be free to renew their waiver argument. Likewise I do not now address Debtor's objection that the claim was in an unspecified amount, and Claimants' response and request that I order the Debtor to produce payroll records so that the Claimants could determine the estimated claim amount.
- ⁶ While I do not find Claimants' delayed filing of the Motion fatal to its cause today, I express no opinion on whether their failure to act in connection with the class nature of their claim may ultimately present a barrier to participation in this estate. As noted above, that issue is reserved for another day.
- ⁷ This Objection was one of eighteen it brought on March 25, 2003 alone, four months after plan confirmation, presumably as part of a claims objection program.
- ⁸ Class 7, general unsecured claims, is to share in a fund of \$5,000,000 ten days after the effective date of the plan. That distribution has been paid and no reserve was made for the Claimants' claim. The Disclosure Statement states that the unsecured claims total approximately \$12,518,937.88 and that after the payment of the \$5,000,000, an additional \$16,923,613.44 would be available for distribution to unsecured creditors so that they would be paid in full. Fourth Amended Disclosure Statement at 11 (Doc. No. 314). If these liquidation values hold, the class claim would have to be allowed in an amount in excess of \$9,000,000 to effect the otherwise 100% distribution to unsecured creditors.

Exhibit 7

In re Tarragon Corp., No. 09-10555 DHS,
2010 WL 3842409 (Bankr. D.N.J. Sept. 24, 2010)

In re Tarragon Corp., Not Reported in B.R. (2010)

2010 WL 3842409

Only the Westlaw citation is currently available.
NOT FOR PUBLICATION
United States Bankruptcy Court, D. New Jersey.

In re TARRAGON CORPORATION, et al.,
Debtors-in-Possession.
Lymarie Rodriguez, et al., Claimants,
v.
Tarragon Corporation, et al., Defendants.

No. 09-10555 DHS.
|
Sept. 24, 2010.

Attorneys and Law Firms

Paul L. Orshan, P.A., [Paul L. Orshan](#), Esq., Coral Gables, FL, for Claimant on behalf of herself and others similarly situated.

Kelly & Brennan, P.C., [Andrew J. Kelly](#), Esq., Spring Lake, NJ, for Claimant on behalf of herself and others similarly situated.

Cole Schotz Meisel Forman & Leonard, P.A., [Michael D. Sirota](#), Esq., [Warren A. Usatine](#), Esq., [Ilana Volkov](#), Esq., Court Plaza North, Hackensack, NJ, for Defendants.

Forman Holt Eliades & Ravin, LLC, [Harry Gutfleish](#), Esq., Paramus, NJ, for the Secured Creditors' Committee.

information to purchasers of condominium units at Vista Lakes in Orlando, Florida. The Claimant sought relief in Florida state court before the Debtor/Defendants filed bankruptcy. Thereafter, she dropped those claims asserted in the state court action and timely filed five identical proofs of claim with this Court.

The Debtor/Defendants argue that the Claimant (1) provided insufficient supporting documentation, (2) has not and could not obtain class certification after a delay in seeking certification, (3) has not complied with [Federal Rule of Bankruptcy Procedure 2019](#), and (4) that the claims are impermissibly duplicative. The Claimant asserts that her class claims meet the requirements of [Federal Rule of Civil Procedure 23](#). Further, she argues that the delay is justified because certification may not be sought until objection is made and that a [Rule 2019](#) filing is not necessarily needed in the case of a class action. For the reasons that follow, the Court grants the Debtor/Defendants' motion to expunge the class proofs of claim.

The Court has jurisdiction over this motion pursuant to [28 U.S.C. § 1334](#) and the Standing Order of Reference from the United States District Court for the District of New Jersey dated July 23, 1984. This matter is a core proceeding pursuant to [28 U.S.C. § 157\(b\)\(2\)\(A\), \(B\), and \(O\)](#). Venue is proper under [28 U.S.C. §§ 1408 and 1409](#).

PROCEDURAL HISTORY AND STATEMENT OF FACTS

On or about July 9, 2008, the Claimant filed a class action complaint against Debtors Tarragon Corp., Tarragon Development Corp., TDC, TMI, and Vista Tarragon ("Defendants") in the Circuit Court, Ninth Judicial Circuit of Orange County, Florida.¹ (Defs.' Br. in Supp. of Mot. to Expunge 4.) The complaint alleged that the Defendants did not disclose that condominium units offered for sale and subsequently purchased at Vista Lakes in Orlando, Florida ("Vista Lakes") were near a former Army bomb testing facility.² (*Id.* at 5.) On January 12–13, 2009, the Defendants filed a chapter 11 bankruptcy in this Court. (Pl.'s Br. in Opp'n to Mot. to Expunge 3.)

OPINION

[DONALD H. STECKROTH](#), Bankruptcy Judge.

*1 Before the Court is the Debtor/Defendants' motion to expunge purported class proofs of claim filed by Lymarie Rodriguez, also known as Lynnmarie Rodriguez ("Claimant"), on behalf of herself and others similarly situated. The class claims stem from the Debtor/Defendants' alleged failure to disclose pertinent

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On February 13, 2009, the Defendants filed suggestions of bankruptcy with the Florida state court. (Defs.' Br. in Supp. of Mot. to Expunge 5.) On March 5, 2009, this Court entered an order fixing May 4, 2009 as the date by which non-governmental creditors had to file a proof of claim against Tarragon or any related entities. (*Id.* at 3.) On March 13, 2009, the Claimant, along with all other Vista Lake residents and known creditors of Vista Tarragon, were subsequently informed by Kurtzman Carson Consultants ("KCC"), the Claims and Noticing Agent for the Debtors' estates, of the May 4 bar date. (*Id.* at 5.) On April 5, 2009, in state court, as a consequence of the automatic stay, the Claimant filed a second amended complaint that did not assert claims against the Defendants, but stated "[Claimant] will maintain her claims against the Debtor[] [Defendants] in ... bankruptcy court." (Pl.'s Br. in Opp'n to Mot. to Expunge 5.) (Pl.'s Sec. Am. Compl. at 2 n. 1.)

*2 On May 2, 2009, the Claimant filed five identical proofs of claim on behalf of herself and others similarly situated. (Defs.' Br. in Supp. of Mot. to Expunge 2-3) The Claims were brought against TDC, Vista Tarragon, TMI, Tarragon Development Corp., and Tarragon Corp., each in the amount of \$50,000,000 for "Breach, Rescission, [and] Fraud." (*Id.*) The Claimant attached the second amended complaint from the state action as support for her proof of claim. As noted above, the second amended complaint makes no assertions or allegations against the Defendants. (*Id.* at 11.) Instead, it announces her intent to pursue the claims in bankruptcy court. (Pl.'s Br. in Opp'n to Mot. to Expunge 5.) Lastly, the Claimant has neither been granted nor has she moved for class certification in this Court.³ (Defs.' Br. in Supp. of Mot. to Expunge 14.)

At present, the Defendants seek an order expunging the class proofs of claim pursuant to 11 U.S.C. § 502(b) and Federal Rule of Bankruptcy Procedure 3007.

I. Class Proof of Claims

DISCUSSION

The right to file a proof of claim is governed by § 501 of the Bankruptcy Code. 11 U.S.C. § 501. Class proofs of claims are not specifically allowed under § 501. Still, the majority of courts agree that such claims are permissible in a bankruptcy case. *In re Spring Ford Industries*, Case No. 02-15015, 2004 Bankr.Lexis 112, at *6 (Bankr.E.D.Pa. Jan. 20, 2004); See *In re Musicland Holding Corp.*, 362 B.R. 644, 650 (Bankr.S.D.N.Y.2007). While “[t]he class proof of claim device may be utilized in appropriate contexts, [] such contexts should be chosen most sparingly.” *In re Sacred Heart Hospital of Norristown*, 177 B.R. 16, 22 (Bankr.E.D.Pa.1995).

After filing a class proof of claim, a claimant will usually file a motion for class certification to obtain the benefit of Federal Rule of Civil Procedure 23, pursuant to Bankruptcy Rule 7023. The timing and procedural context in which such motion must be made varies by jurisdiction. The Eleventh Circuit has held that a motion for class certification cannot be made until an objection to the class proof of claim is filed. See *In re Charter Co.*, 876 F.2d 866 (11th Cir.1989). Courts in the Southern District of New York have rejected this proposition stating “such a construction … would mean that a debtor … could prevent the claimant from asking the bankruptcy court to apply Rule 23 simply by withholding their objections until the eve of confirmation and then move to expunge the class claim on the grounds that applying Rule 23 would unduly delay distribution.” *In re Ephedra Prods. Liab. Litig.*, 329 B.R. 1, 6 (S.D.N.Y.2005).

In accord with the Southern District of New York, this Court has held a motion for class certification was timely when filed *with* a proof of claim. *In re First Interregional Equity Corp.*, 227 B.R. 358 (Bankr.D.N.J.1998). Thus, the applicability of Rule 7023 is ripe and appropriately considered at this stage.

II. Applicability of Federal Rule of Civil Procedure 23

*3 Class actions are governed by Federal Rule of Civil Procedure 23, applicable in bankruptcy proceedings through Bankruptcy Rule 7023. Fed.R.Civ.P. 23; Fed. R. Bankr.P. 7023. Generally, “class proofs of claims should be permitted … when the bankruptcy judge has exercised his or her discretion under Rule 9014 to apply

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Rule 23 to a contested matter.” *In re Zenith*, 104 B.R. 659, 664 (Bankr.D.N.J.1989). However, “[b]ankruptcy significantly changes the balance of factors to be considered in determining whether to allow a class action and ... class certification may be ‘less desirable in bankruptcy than in ordinary civil litigation.’” *Ephedra*, 329 B.R. at 5 (quoting *In re American Reserve Corp.*, 840 F.2d 487, 493 (7th Cir.1988)). In fact, a class action may be certified in a non-bankruptcy court and yet be subsequently disallowed to proceed in class form in the bankruptcy setting. *In re Zenith*, 104 B.R. at 664.

In cases where a Rule 23 determination is not timely made in another court, the bankruptcy court must first decide whether Rule 7023 should be invoked. *In re Craft*, 321 B.R. 189, 198 (Bankr.N.D. Texas 2005). In determining whether or not to make Rule 7023 applicable, the court may exercise its sound discretion. See *Reid v. White Motor Corp.*, 886 F.2d 1470 (“Rule 9014 delegates wide discretion to the bankruptcy judge in considering certification of class proofs of claim pursuant to Rule 7023 in a contested matter.”).

The Bankruptcy Code and Rules do not offer express guidance on the applicability of Rule 23. However, a “pervasive theme is avoiding undue delay in the administration of the case.” *Ephedra*, 329 B.R. at 5. There is no bright-line rule setting the clock within which a claimant must move for certification. Rather, the facts determine when a delay is undue. See *Spring Ford*, 2004 Bankr.Lexis 112, at * 15 (finding a motion timely when filed a year after the class proof of claim); *In re Woodward & Lothrop Holdings, Inc.*, 205 B.R. 365, 370 (Bankr.S.D.N.Y.1997) (motion for class certification never made); *In re Fleet*, 76 B.R. 1001, 1004 (Bankr.E.D.Pa.1987) (allowed claimants’ motion for certification four years after filing their complaint).

III. Undue Delay

Federal Rule of Civil Procedure 23(c)(1) requires that class certification be sought “[a]s soon as practicable after the commencement of an action brought as a class action....” Fed.R.Civ.P. 23(c)(1). Though “[a] delay does not automatically disqualify the class claim, it bears

on the exercise of the discretion whether to apply Rule 23.” *In re Musicland*, 362 B.R. at 652; See *In re Thomson McKinnon Securities, Inc.*, 150 B.R. 98, 101 (Bankr.S.D.N.Y.1992) (class claim expunged for failure to fulfill requirements of Rule 23). “We believe that the more thoughtful cases on this topic focus upon two considerations: (1) Does the moving party have a justifiable reason for the delay? and (2) Is the opposing party unfairly prejudiced by the delay? We should further observe that we consider the second of these questions to be the more important of the two.” *In re Fleet*, 76 B.R. at 1006.

*4 In bankruptcy, a “delay may impact the entire case—not just the affected claim—and provides grounds for a bankruptcy court to refuse to make Rule 23 applicable to the claims process.” *Woodward*, 205 B.R. at 370. “As the case in chief moves toward its conclusion, it is more likely that a delay in resolving the certification issue will interfere with the administration of the estate.” *Id.* If the claimant waits until a post confirmation claim objection to first bring the issue to the court, serious prejudice may result to the other creditors and the estate.⁴ *Id.* In addition, prejudice to the debtor is compared with any prejudice that may befall other stakeholders, including potential plaintiffs. See *In re Fleet*, 76 B.R. at 1007. The judicial gloss on when the court—should or should not—exercise its discretion is of little help,

[t]hose courts that would equate the determination of a class under Rule 7023 with the determination of whether to apply Rule 7023 do not recognize the concerns peculiar to bankruptcy law—which are the appropriate bases for exercise of discretion under Rule 9014. These concerns properly include, to a greater or lesser degree, prejudice to the debtor or its other creditors, prejudice to putative class members, efficient estate administration, the conduct in the bankruptcy case of the putative class representatives, and the status of proceedings in other courts.

In re Craft, 321 B.R. at 198–199; See *Reid*, 886 F.2d at 1470–71 (affirming bankruptcy court’s denial of class proof of claim because attorney failed to timely petition bankruptcy court to apply Rule 7023).

In *Fleet*, the court agreed that a timely class determination would have been more effective in notifying unnamed class plaintiffs than would be the case if certification were granted five or so years after the defendants closed shop. *In re Fleet*, 76 B.R. at 1006. Despite the delay, the court

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found that since the defendants were no longer doing business, the only practical relief for the unnamed plaintiffs was strictly monetary relief. *Id.* at 1001. Thus, the bankruptcy court allowed a certification motion to proceed where expungement would cause “extreme prejudice” to the unnamed class plaintiffs. *Id.* at 1007.

In the instant matter, no such prejudice to the Claimant, or any members of the putative class, is apparent. The plaintiffs, named or unnamed, received actual notice of the claim bar date by KCC. Though they may not have known of the Claimant’s class proofs of claim, they had an opportunity to investigate and pursue potential individual claims and did not do so.

Here, the claim may have been permissible if the Claimant could justify the delay. However, the Claimant has not alleged any facts adequate to provide justification for her delay in bringing a motion for class certification. Finally, and most importantly, we consider prejudice to the Defendants caused by the delay. A Plan of Reorganization has been confirmed with support of all creditor groups and subsequently implemented by the Defendants. “[T]he granting of class action claims at this late juncture would wholly disrupt and undercut the expeditious execution of the Plan of Reorganization.”

 *Ephedra*, 329 B.R. at 4. The claims filed by the Claimant are not insignificant as filed. The requested relief numbers in the tens of millions and would undoubtedly upset the administration of the Defendants’ Plan.

*5 Consequently, applying  Rule 23 at this late stage would be wholly inconsistent with the efficiency goals of the Bankruptcy Code. Here, more than a year after the class proof of claim was filed, the Claimant has yet to move for the application of  Federal Rule of Civil

Procedure 23 pursuant to Bankruptcy Rule 7023. A class action under these facts works in opposition to the goals of bankruptcy. Not only has there been no pre-petition, non-bankruptcy certification,⁵ but the putative class was given actual notice of the Defendants’ bankruptcy case and claim bar date. If allowed to proceed, the Claimant’s unexplained delay in moving for class certification would inflict unjustifiable harm on the Defendants and their other creditors. Thus, for the above reasons, the Court will deny application of Bankruptcy Rule 7023.

CONCLUSION

Though a class proof of claim may be filed in a bankruptcy court, a claimant must move for class certification without undue delay. Undue delay has occurred where a claimant has not justified the delay and allowing the class to continue would cause prejudice to the debtor and its creditors. Here, the Claimant has failed to justify her inactivity in pursuing her claims in this Court. Further, and most notably, allowing the claims to continue would be prejudicial to the Defendants and their creditors. Thus, the Defendants’ motion to expunge the class proof of claims is granted.

An Order in conformance with this opinion has been entered by the Court and a copy attached hereto.

All Citations

Not Reported in B.R., 2010 WL 3842409

Footnotes

¹ *Lymarie Rodriguez v. Tarragon Corp., et al.*, Case No. 48-2008-CA-016343-O

² As of March 17, 2009, after the Florida state court entered an order dismissing certain claims against the Defendants, the only claims that survive the order are purportedly nondisclosure and deceptive acts or practices against only Vista Tarragon. (Pl.’s Br. in Opp’n to Mot. to Expunge 6-7.)(Certif. of Robert Robbins ¶ 8-9.)

³ On December 3, 2009, the Florida state court entered an order to stay the state court action pending the outcome of another matter, known as the Virgilio Matter, which involves identical claims and has reached the class certification stage. Thus, the Claimant has not yet been considered for class certification in the state action. (Defs.’

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Br. in Supp. of Mot. to Expunge 8.)

- ⁴ The *Woodward* court, ultimately denying class certification, found prejudice precluding the applicability of Rule 23. The movant never moved for certification and the court noted that a liquidating plan had been confirmed and the debtor sold all assets, making an approximate 70% distribution to unsecured creditors. “If the debtor must now spend the time and money litigating the class certification questions and paying a class claim, this may jeopardize further distributions, and eventually, require disgorgement.” *Woodward*, 205 B.R. at 370.
- ⁵ Even where a non-bankruptcy court has certified a class, “there may be other factors in the bankruptcy proceeding that make class certification there less compelling and it may be possible that a different result might be appropriate.” *In re Zenith*, 103 B.R. at 664; See *American Reserve*, 840 F.2d at 493–494; See also *Reid v. White Motor Corp.*, 886 F.2d at 1470–71 (affirming bankruptcy court’s denial of class proof of claim because attorney failed to timely petition bankruptcy court to apply Rule 7023).

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Exhibit 8

Int'l Union v. Ford Motor Co., Nos. 05-74730, 06-10331,
2006 WL 1984363 (E.D. Mich. July 13, 2006)

International Union v. Ford Motor Co., Not Reported in F.Supp.2d (2006)

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2006 WL 1984363
United States District Court,
E.D. Michigan, Southern Division.

INTERNATIONAL UNION, United Automobile, Aerospace, and Agricultural Implement Workers of America, and Bobby Hardwick, Carl Malfitano, Walter Berry, Raymond J. Mitchell, Fay Barkley, Arlen Banks, and Yvonne Hicks, on behalf of themselves and all other persons similarly situated, Plaintiffs,

v.

FORD MOTOR COMPANY, Defendant.

Nos. 05-74730, 06-10331.

|
July 13, 2006.

*FINDINGS OF FACT AND CONCLUSIONS OF LAW
APPROVING THE CLASS ACTION SETTLEMENT,
FINDING THAT THE SETTLEMENT IS FAIR,
REASONABLE, AND ADEQUATE PURSUANT TO
FED. R. CIV. P. 23(e)(1)(C)*

BORMAN, J.

*1 Now before the Court is a health care benefits class action lawsuit. The contesting parties have presented this Court with a proposed settlement agreement. The Court held a  Federal Rule of Civil Procedure 23(e)(1)(C) Fairness Hearing regarding the proposed settlement agreement on May 31, 2006. At the hearing, the Court heard arguments from counsel for the parties (Case No. 05-74730), from counsel for objectors Bronson, *et al.* (Case No. 06-10331), and from counsel for objector Lapso, and the Court heard the specific objections of twenty-five (25) individual objectors who had expressed a desire to be heard.

At the conclusion of the Fairness Hearing, the Court requested that the parties submit joint proposed findings of fact and conclusions of law, and the parties did so on June 14, 2006. Objectors' counsel were then given an

opportunity to respond to the joint proposed findings of fact and submit alternative proposed findings of fact and conclusions of law. The Bronson objectors filed a Response on June 23, 2006.

The Court has examined the proposed findings and conclusions, the objectors' responses to the proposed findings and conclusions, as well as the additional material (i.e., documentary evidence, affidavits, etc.) supplied by the parties during the pendency of this litigation. The Court has also taken into consideration the positions stated by those individual objectors who presented views to the Court in writing or presented oral comments to the Court at the Fairness Hearing.¹

The Court now makes the following findings of fact and conclusions of law that govern and conclude this litigation.

I. FINDINGS OF FACT

A. Background

1. Defendant Ford Motor Company ("Ford") and Plaintiff UAW are parties to a series of collective bargaining agreements ("CBAs"), under which Ford provides health care benefits to active hourly workers and to eligible hourly retirees and their spouses, surviving spouses, and dependents. (Am.Compl. ¶ 13) Plaintiffs Bobby Hardwick, Carl Malfitano, Walter Berry, Raymond J. Mitchell, Fay Barkley, and Arlen Banks are former UAW hourly employees of Ford who have retired. (*Id.* ¶¶ 6-11) Plaintiff Yvonne Hicks is the surviving spouse of a deceased UAW hourly employee. (*Id.* ¶ 12)

2. In 2005, Ford announced its decision to unilaterally modify the health benefits of retired hourly employees. (*Id.* ¶ 26) On December 13, 2005, named plaintiffs Hardwick, Malfitano, and Berry, on behalf of a class of retired Ford hourly employees and their spouses, surviving spouses and dependents (hereafter referred to

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collectively as “retirees” unless otherwise indicated) joined with the UAW to commence this declaratory judgment action against Ford. On December 27, plaintiffs filed an Amended Complaint adding Mitchell, Barkley, Banks, and Hicks (referred to collectively with Plaintiffs Hardwick, Malfitano and Berry as “class representatives”) as named Plaintiffs.

3. As set forth in the Amended Complaint, other than Plaintiff Hicks, all of the individual Plaintiffs are Ford retirees. (Am.Compl.¶¶ 6-11) Mrs. Hicks is the surviving spouse of a Ford retiree. (*Id.* ¶ 12) The six retiree plaintiffs had, in the past, been elected by fellow retirees to serve on various retired worker councils and chapters. (*Id.* ¶¶ 6-11)

*2 4. More particularly, Plaintiff Hardwick was employed by Ford in Lorain, Ohio, and was a member of the bargaining unit represented by the UAW until his retirement in 1997. In March 2004, Mr. Hardwick was elected chairperson of the UAW Eastern Kentucky Retired Workers Council, which is part of the UAW Region 3 Area Retired Workers Council. (Docket No. 878, Ex. 7, Hardwick Decl.)

5. Plaintiff Malfitano was employed by Ford in Sterling Heights, Michigan, and was a member of the bargaining unit represented by the UAW until his retirement in 1992. After his retirement from Ford, Mr. Malfitano was appointed Chairperson of the UAW Region 1 Retired Workers Council, which covers several counties in Michigan. (Docket No. 878, Ex. 8, Malfitano Decl.)

6. Plaintiff Berry was employed by Ford in Indianapolis, Indiana, and was a member of the bargaining unit represented by the UAW until his retirement in 1987. Mr. Berry serves as the chairperson of the Local 1111 Retired Workers Chapter. (Docket No. 878, Ex. 9, Berry Decl.)

7. Plaintiff Mitchell was employed by Ford in Wayne, Michigan and Allen Park, Michigan, and was a member of the bargaining unit represented by the UAW until his retirement in 1998. In 1999, he was elected chairperson of the UAW Local 931 Retired Workers Chapter. (Docket No. 878, Ex. 10, Mitchell Decl.)

8. Plaintiff Barkley was employed by Ford in Sterling Heights, Michigan, and was a member of the bargaining unit represented by the UAW until her retirement in 1988. In 1994, Mrs. Barkley was elected chairperson of the UAW Local 2280 Retired Workers Chapter. (Docket No. 878, Ex. 11, Barkley Decl.)

9. Plaintiff Banks was employed by Ford in Long Beach, California, and Pico Rivera, California until his retirement in 1980. In approximately 1995, he was elected chairperson of the UAW Region 5 Area Retired Workers Council, which covers Southern California. (Docket No. 878, Ex. 12, Banks Decl.)

10. Plaintiff Hicks’s late husband Samuel Hicks worked for Ford at its Sharonville, Ohio, facility. He retired in 1980 and passed away in 2005. (Docket No. 878, Ex. 13, Hicks Decl.)

11. On January 24, 2006, Objector Lawrence Bronson and two other Ford/UAW retirees filed a complaint titled *Bronson, et al. v. Ford Motor Co.*, Civ. A. No. 06-10331 (E.D.Mich.), asserting the same claims and seeking the same relief as the class in this action. (See Bronson Compl., Civ. A. No. 06-10331, Docket No. 1, at 1-2) The Bronson complaint also sought, pursuant to [Federal Rule of Civil Procedure 23\(b\)\(2\)](#) and [23\(b\)\(3\)](#), to certify a class defined substantially identical to the class originally alleged by the Hardwick plaintiffs and to have Mr. Bronson’s counsel, Mark Baumkel, Steven Schwartz and Daniel Scott, named as Class Counsel. (See *id.* at 3-4, 11) On January 25, 2006, Bronson also moved to intervene in this action. (See Docket No. 6, Mot. to Intervene)

12. On February 6, 2006, class representatives filed a motion seeking certification of a class of Ford retirees, spouses, surviving spouses, and dependents; class representatives also sought appointment of Class Counsel. (Docket No. 16, Mot. for Class Certification)

*3 13. On February 13, 2006, after Class Counsel had completed their investigation and given their recommendation to class representatives, the parties entered into a Settlement Agreement. (See Docket No. 24, Ex.

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1. Proposed Settlement Agreement Preamble; *see also* Docket No. 878, Exs. 7-13 (class representatives' declarations)) Over the preceding weeks, the parties negotiated the terms of the Agreement. Class Counsel fully participated in these negotiations. During the negotiations, as an example, Ford demanded that it be able to re-coup monthly premium payments from retirees and surviving spouses who might be improperly placed in the protected group (*i.e.*, those participants who are not subject to monthly premium payments, co-pays, and deductibles). (*Id.* ¶ 23) The UAW and Class Counsel resisted this demand, and the Settlement Agreement does not permit Ford to retroactively charge such individuals. On the same date, the parties submitted their proposed Settlement Agreement to the Court and asked the Court to preliminarily approve the proposed Settlement and order that notice of the settlement be sent to class members. (Docket No. 24, Jt. Mot. for Prelim. Approval)

14. The instant case was initially assigned to United States District Judge Arthur Tarnow. On February 24, 2006, Judge Tarnow provisionally certified a class, and approved the named plaintiffs as representatives of the class and their counsel as counsel to the class. (Docket No. 36, Order) Judge Tarnow defined the class as:

All persons who, as of December 22, 2005, were (a) Ford/UAW hourly employees who had retired from Ford with eligibility to participate in retirement in the Ford Hospital-Surgical-Medical-Drug-Dental-Vision Program ("Plan"), or (b) the spouses, surviving spouses and dependents of Ford/UAW hourly employees, who, as of December 22, 2005, were eligible for post-retirement or surviving spouse health care coverage under the Plan as a consequence of a Ford/UAW hourly employee's retirement from Ford or death prior to retirement.

(Docket No. 36, Order ¶ 8).

15. Judge Tarnow ruled that all of the requirements of Rule 23(a) were satisfied and that the class was properly certified under Rule 23(b)(2).

16. The Court certified the following class:

All persons who, as of December 22, 2005, were (a) Ford/UAW hourly employees who had retired from Ford with eligibility to participate in retirement in the Ford Hospital-Surgical-Medical-Drug-Dental-Vision Program ("Plan"), or (b) the spouses, surviving spouses and dependents of Ford/UAW hourly employees, who, as of December 22, 2005, were eligible for post-retirement or surviving spouse health care coverage under the Plan as a consequence of a Ford/UAW hourly employee's retirement from Ford or death prior to retirement. (*Id.*)

17. Also in this Order, the Court appointed attorneys William T. Payne, John Stember, and Edward J. Feinstein as Class Counsel, finding that:

*4 [T]hese attorneys will fairly and adequately represent the interests of the class, in consideration of the work counsel has done in identifying or investigating potential claims in this action, counsel's experience in handling class actions, other complex litigation, and claims of the type asserted in this action, counsel's knowledge of the applicable law, and the resources counsel will commit to representing the class. (*Id.*)

18. The Court also preliminarily approved the Settlement Agreement by Order dated February 24, 2006. (Docket No. 35) The Court concluded:

The Settlement Agreement (at exhibit 1 to the parties' Joint Motion for Preliminary Approval) is preliminarily approved. The Court finds that the proposed settlement falls within the range of possible approval, does not disclose grounds to doubt its fairness, and includes no obvious deficiencies.

19. The Court also directed Ford to use its best efforts to send notice to individual class members by March 10, 2006. The form of Notice sent to class members is attached to the Passarella Declaration. (Docket No. 882, Ex. F, Passarella Decl.) Along with the Notice, class members were also sent the actual Settlement Agreement. The Notice includes a brief

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summary of the Agreement, advising that much “technical detail” was omitted from the Notice, urging class members to read the Agreement carefully, and explaining that if there were any inconsistencies between the Notice and the Agreement, the Agreement would govern. (Docket No. 882, Ex. F, Passarella Decl. Ex.1, Class Notice at 5, 19) The Court-approved Notice also explained precisely how objections were to be submitted and that any objecting class member could tell the Court in person why he or she believed the settlement should not be approved. (*Id.* at 17) The Notice was sent to class members along with a cover letter from Class Counsel and the UAW that provided additional information about the settlement. (*See id.*) Notice was also published in *USA Today*, the *Detroit News* and the *Detroit Free Press*. (Docket No. 882, Ex. G, Kuzma Decl. ¶¶ 3-5)

20. Also on February 24, 2006, after preliminarily approving the proposed Settlement, certifying the Hardwick class, and appointing Messrs. Payne, Stember, and Feinstein as Class Counsel, the Court denied Bronson’s motion for intervention. (Docket No. 37, Order Denying Mot. to Intervene Without Prejudice) Thereafter, on February 28, 2006, the Court issued an order consolidating the *Bronson* action with this action.² (*Bronson v. Ford*, Civ. A. No. 06-10331, Docket No. 11, Order Consolidating Cases)

21. On March 23, 2006, Class Counsel filed a motion for attorneys’ fees and expenses. (Docket No. 131) On July 12, 2006, this Court entered an Order granting Class Counsel’s Motion for Attorney Fees.

B. Plaintiffs’ Claims And Ford’s Defenses

22. In their Amended Complaint, plaintiffs alleged that under the CBAs, plaintiffs’ health benefits are vested, and that Ford “may not unilaterally terminate or modify those benefits.” (Am.Compl.¶¶ 23, 25) According to plaintiffs, Ford’s decision to modify benefits is an “anticipatory repudiation” of its “contractual obligation” under the CBAs and “its obligations as plan sponsor and administrator” of an

employee welfare plan. (*Id.* ¶¶ 29, 32)

*5 23. In Count I, brought under Section 301 of the Labor Management Relations Act, [29 U.S.C. § 185](#), plaintiffs seek an injunction and a declaration that retiree health care benefits cannot be unilaterally terminated or modified by Ford. (*Id.* ¶¶ 3, 28-30) The plaintiffs also seek the same relief in Count II, under Section 502(a)(1)(B), (a)(3) of the Employee Retirement Income Security Act of 1974 (“ERISA”), [29 U.S.C. § 1132\(a\)\(1\)\(B\), \(a\)\(3\)](#). (*Id.* ¶¶ 4, 31-33)

24. Ford filed its Answer and Affirmative Defenses on January 17, 2006. Ford denies that the retiree health care benefits it provides are vested benefits that cannot be unilaterally modified or terminated by Ford. (Docket No. 4, ¶ 26) Ford asserts affirmative defenses, including that plaintiffs’ claims are barred by the terms of the CBAs, as well as by acquiescence, waiver, ratification and/or estoppel. (*Id.* Affirm Def. ¶¶ 1-9)

C. Ford’s Financial Crisis

25. In recent years, Ford has faced increasingly difficult financial problems, stemming largely from its core business, North American auto manufacturing. In 2005, Ford’s global automotive operations lost \$1.0 billion, and virtually all of the loss was experienced in North America. (*See* Docket No. 882, Ex. C, Gouin Decl. ¶ 3) First quarter results for 2006 show a loss of \$0.5 billion-\$1.1 billion less than first quarter 2005. (*Id.*) Even though Ford’s worldwide automotive operations lost \$1.0 billion, the company had a \$2.0 billion profit last year due to the performance of the financing side of Ford’s business. (*Id.* ¶ 2)

26. Ford’s automotive operating cash flow—the cash flow generated by Ford’s automotive business—has also substantially declined. In 2005, Ford experienced negative automotive cash flow of \$1.3 billion (excluding the \$0.4 billion cost of employee separation programs). (*See id.* ¶ 4). In the first quarter of 2006, cash flow has continued to deteriorate, with Ford

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already experiencing \$0 .7 billion negative cash flow (excluding \$0.5 billion cost of separation programs). (*See id.*)

27. Ford's market share position in the U.S. automotive market has declined significantly, dropping to 17% in 2005 from 25% only ten years ago. (*Id.* ¶ 5) Among the reasons for Ford's decline in market share is that many of the brands with which Ford is now competing—including Infinity, Lexus, Acura, and Scion—do not have the legacy expenses of long-standing U.S. automakers like Ford, and therefore enjoy a substantial pricing and competitive advantage. (*Id.*)

28. Ford's financial and competitive problems have also affected the value of its business. In 2001, Ford's market capitalization—a measure of value determined by the market price of its outstanding shares of stock—stood at \$54 billion. (*Id.* ¶ 6) By 2005, it had dropped almost 75%, to only about \$14 billion. (*Id.*) To put that present market value in relevant context, Ford's total market capitalization is now only 40% of the present value of its future post-retirement non-pension benefits. (Docket No. 882, Ex. A, Benson Decl. ¶ 9) The present value of Ford's future retirement benefits, typically referred to as either accumulated post-retirement benefits obligation ("APBO") or other post-employment benefits obligation ("OPEB"), was \$37 billion in 2005, and virtually all of that, \$35 billion, is attributable to retiree health care costs. (*Id.* ¶ 7) Over the same period, Ford's stock price has dropped from \$30 per share in March 2001 to \$6.80 per share as of July 11, 2006. (Docket No. 882, Ex. C, Gouin Decl. ¶ 6)

*6 29. Market capitalization, APBO and loss of market share also influence how credit analysts view the company. As recently as 2000, Ford's credit rating was "A+," but by May 2005 the rating had been downgraded to non-investment or "junk" levels by both Standard & Poor's and Moody's, the two leading debt rating agencies. (*Id.* ¶ 7) As one of the reasons for the downgrade, credit rating agencies cited Ford's massive retiree health care expense, reflecting their uncertainty that Ford can meet its financial obligations under certain conditions. (*Id.* ¶ 8; see also Docket No. 24, Jt. Mot. For Prelim.

Approval, Ex. 2) Just recently, Fitch Rating downgraded Ford's rating from BB to B+. J. McCracken, *Ford's Debt Rating Is Downgraded Two Notches*, Wall Street Journal, Jun. 9, 2006 at A3.

30. Ford's deteriorating credit rating has several adverse effects on Ford's financial position. It limits the Company's access to capital and substantially increases the cost of borrowing, making it more difficult for Ford to generate revenue and invest in new products and other business development. (*Id.* ¶ 9) It worsens Ford's competitive position, because most of Ford's competitors do not face the same constraints. (*Id.* ¶ 10) And importantly, it also reduces the positive net income generated by Ford's finance and lending arm, Ford Credit. (*Id.*) In recent years, Ford Credit has provided the primary positive contribution to Ford's financial performance, accounting for all of the company's cumulative consolidated profits since 2001. (*Id.*) Because of the downgrades, Ford Credit's overall cost of borrowing has significantly increased, and it has been forced to shift from unsecured funding to asset-backed borrowing. (*Id.*) Ford Credit's business is largely dependent on financing Ford's automotive sales, which are declining in market share. (*Id.*) And Ford's financial position will also be affected by the recent sale of Hertz car rental to raise needed cash. (*Id.* ¶ 12)

D. Impact Of Health Care Expense On Ford's Financial Performance

31. Ford provides health care benefits to approximately 590,000 employees, retirees, and their dependents in the United States. (Docket No. 882, Ex. A. Benson Decl. ¶ 4) In 2005, the company spent \$3.5 billion on health care, of which over two-thirds, or \$2.4 billion, was spent on health care for Ford retirees. (*Id.*) Health care expense is rapidly escalating. Ford's total health care expense has increased 67% since 2000, and retiree health care accounted for some 80% of that increase. (*Id.* ¶ 5)

32. Looking at health care costs from another perspective, Ford spent some \$1,100 per vehicle

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on health care in 2005-more than the per-vehicle cost of steel. (*Id.* ¶ 6) Over two-thirds of this per-vehicle cost was attributable to retiree health care. (*Id.*) This huge cost represents a significant competitive disadvantage, because many of Ford's foreign competitors do not bear the substantial legacy costs of retiree health care. For example, Japanese automakers that manufacture and sell their products in the United States bear a per-vehicle cost of only \$450 to provide health care for both active and retired personnel-less than half the level Ford pays. (*Id.*)

*7 33. Ford's \$37 billion APBO is one of the largest among U.S. companies, according to information obtained from available Securities and Exchange Commission 10-K filings for publicly held companies. (*Id.* ¶ 9) Across Fortune 50 companies, APBO liability is on average less than 10% of either revenues or market capitalization. (*Id.*) In contrast, as of December 31, 2005, Ford's APBO was nearly 300% of the value of the company itself as measured by the market value of its outstanding shares of stock, and was equal to almost 40% of its annual sales. (*Id.*)

E. The UAW's History Of Fighting For Retirees

34. The UAW has a long and storied history of defending the interests of retirees-including particularly, retiree health care and other retiree benefits-both at the bargaining table and in the courtroom. For example, during the 1960s the UAW negotiated improvements in health care for already retired employees, with the result that a retiree who left Ford in 1958 under a collective bargaining agreement providing for no Ford contribution to retiree health became entitled by 1967 to Ford's payment of 100% of the premiums for himself and eligible dependents. (Docket No. 896, Bantom Decl. ¶ 6)

35. In addition, the UAW has litigated or funded the litigation of numerous cases on behalf of UAW retirees to preserve retiree benefits. (*Id.* ¶ 7 & Ex. C) The UAW has litigated these cases in trial and appellate courts,

with active workers footing the legal bills through their union dues.

36. UAW active members have historically proven their willingness to devote their bargaining leverage, their dues, and now their scheduled wage increases, to the cause of retiree health benefits for two reasons: because active workers-about one-quarter of whom are facing imminent retirement themselves-recognize that they will benefit from the UAW's advocacy when it comes time for their own retirement, and because they believe it is simply the right thing to do. (*Id.* ¶ 8)

F. The UAW And Class Counsel's Independent Analysis Of Ford's Finances

37. Before Plaintiff UAW agreed to negotiate with Defendant Ford on retiree health care benefits, it insisted that Ford provide full access to Ford's books, including highly confidential financial, manufacturing, purchasing, marketing, personnel, and product information, as well as access to top executives, from which and whom UAW could make an independent analysis of Ford's finances. The UAW retained the investment banking firm of Lazard Frères & Co. LLC ("Lazard") to perform a financial analysis. Lazard's mandate included:

(i) evaluating Ford's financial position and prospects, (ii) analyzing Ford's ability to meet its prospective retiree healthcare obligations and (iii) considering the need for and potential impact of healthcare relief on Ford's financial condition and prospects.

(Docket No. 890, Yearley Decl. ¶ 9)

38. Ford accepted the UAW's conditions and provided the UAW and Lazard with unprecedented access to sensitive confidential information about the Company's financial condition generally and health care expenditures in particular. (See Docket No. 24, Ex. 1, Proposed Settlement Agreement ¶ 3)

*8 39. Lazard's analysis fully confirmed Ford's considerable financial challenges and that Ford was at serious risk of further decline. (See

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Docket No. 879, Bantom Decl. ¶¶ 17-19; Docket No. 879, Yearley Decl. ¶¶ 19-22) On the basis of this independent confirmation of Ford's condition, the UAW agreed to consider entering into an agreement with Ford concerning retiree health care benefits similar to an agreement it had entered into with General Motors ("GM").³ The UAW concluded:

Furthermore, UAW was aware the Ford retiree medical benefits are not funded by sufficient assets held in trust for that purpose, and Ford retirees are directly dependent on the corporation's survival for their continued benefit. If the company's financial situation continued to worsen, even to the point of insolvency, retiree medical benefits could be eliminated altogether. UAW was convinced that if Ford was at significant risk of continuing in a downward financial spiral, it was vastly preferable to accept modified benefits than nothing at all.

(Docket No. 896, Bantom Decl. ¶ 12). The UAW's framework was not automatically binding on the retirees, but was contingent on court approval.

40. Class Counsel also conducted a substantial factual investigation and legal inquiry. Class Counsel was afforded access to all of the information that was provided to the UAW, as well as to the analyses and opinions of the UAW's experts who reviewed this information. (Docket No. 878, Ex. 1; Payne Decl. ¶ 25) Class Counsel also retained their own experts to assist in reviewing the documents provided to them by Ford, UAW and UAW's financial advisors in order to analyze Ford's financial condition. (*Id.* ¶ 11) Class Counsel's independent investigation and analysis included, *inter alia*, review of Ford's financial information and projected financial condition, review and analysis of relevant health care and plan documents and CBAs, and review of material on Ford's health care costs. (*Id.* ¶¶ 26-27; see also Docket No. 24, Ex. 1, Proposed Settlement Agreement ¶ 3) Like counsel for the UAW, Class Counsel also thoroughly reviewed the relevant collective bargaining agreements by which retiree health benefits were created and investigated the law applicable to Ford's unilateral decision to modify retiree health benefits. (Docket No. 878, Ex. 1, Payne Decl.

¶ 25, 29; Docket No. 24, Ex. 1, Proposed Settlement Agreement § 3)

41. Based on their investigation, Class Counsel concluded that Ford is facing very serious financial difficulties and that continuation of a quality retiree medical program depends on Ford remaining a viable company. (Docket No. 878, Ex. 1, Payne Decl. ¶ 28; Docket No. 24, Ex. 1, Proposed Settlement Agreement § 4) Class Counsel further concluded that absent substantial cost-reduction measures, Ford may not survive in a form that allows it to continue to provide comprehensive and high quality retiree medical benefits over the long term. (*Id.*)

G. UAW/Ford Negotiations

*9 42. In December 2005, UAW presented Ford with a package of modest cuts to retiree health benefits. Under this proposal, the most financially vulnerable retirees were protected and Ford was required to mitigate the costs to retirees of these cuts through contributions to a defined contribution Voluntary Employee Benefits Association ("DC-VEBA") trust. (Docket No. 896, Bantom Decl. ¶ 21) Specifically, the proposal protected retirees whose pensions fell below \$8,000 per year (and a benefit multiplier of \$33.33 per month per year of service) from the requirement of any monthly contributions, co-pays, or deductibles. (*Id.* ¶ 21) For retirees with higher pension benefits, the plan called for relatively low drug co-payments, deductibles, and monthly contributions, which were subject to out-of-pocket maximums and a three percent cap on the amounts that these payments could increase annually. (*Id.* ¶ 21) The proposal also included a "case-law standstill" whereby, if Ford later terminated the Settlement Agreement and attempted to unilaterally decrease retiree health benefits, the ensuing litigation would be controlled by the case law as it existed at the time of the agreement's final approval (precedent that UAW deemed favorable to retirees). (*Id.* ¶ 21) Finally, the proposal was also conditioned on UAW active workers voting to agree to contribute their own future contractual wage and cost of living increases, amounting to just under \$1.00 per hour initially, and increasing cumulatively over time with an additional 2 cents per quarter of COLA

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contributions, to the DC-VEBA to mitigate costs to the retirees. (*Id.* ¶ 21)

43. Ford initially requested a 25% reduction in its OPEB liability. (*Id.* ¶ 22) UAW determined that a 25% reduction in Ford's OPEB liability would require that the defined benefit portion of the retirees' health care plan be reduced more than the level the UAW had proposed. (*Id.* ¶ 22) UAW informed Ford that it would not agree to such reductions. Ford eventually agreed to the defined benefit levels proposed by the UAW. (*Id.* ¶ 22) According to Ford's actuaries, this resulted in roughly a 15% reduction in Ford's OPEB liability. (*Id.* ¶ 22)

44. Furthermore, Ford and UAW negotiated over several other aspects of the proposed Settlement. One was the size of Ford's contribution to the DC-VEBA, which Ford attempted to limit to \$35 million. (*Id.* ¶ 23) Eventually, Ford agreed to contribute \$108 million in cash to the DC-VEBA and to make additional contributions if Ford's stock appreciated or Ford issued special dividends. (*Id.* ¶ 23) Ford also unsuccessfully requested that the case-law standstill be softened or eliminated, and that it be allowed to charge higher prescription drug co-pays for mail order drugs than the co-pays set forth in the UAW proposal. (*Id.* ¶ 23) UAW insisted on the lower drug co-pays it had proposed, and Ford ultimately agreed. (*Id.* ¶ 23) Based on the actuarial calculations of its benefits consultants, the UAW determined that at the funding and initial mitigation levels secured by the Settlement, the DC-VEBA is projected to last well beyond twenty years. (*Id.* ¶ 23) Accordingly, UAW agreed to forgo its demand profit-sharing contributions and the contingent possibility of regular dividend contributions (in the event that Ford increased its regular dividends) to the DC-VEBA. (*Id.* ¶ 23)

***10** 45. The parties' negotiations resulted in a Memorandum of Understanding on December 14, 2005, that was ratified in a vote by Ford's active hourly UAW workforce on December 22, 2005, and ultimately culminated in a detailed Settlement Agreement on February 13, 2006, contingent on court approval pursuant to

 Federal Rule of Civil Procedure 23. (*Id.* ¶

24). Class Counsel participated in negotiation of the Settlement Agreement.

H. Memorandum Of Understanding ("MOU")

46. The MOU (Docket No. 879, Ex. 1), which laid out the basic framework for settlement, was ratified, albeit by a slim margin, in a vote of active Ford UAW employees on December 22, 2005. (Docket No. 24, Ex.1, Proposed Settlement Agreement ¶ 5)

47. Under the terms of the MOU, active Ford hourly employees will defer wages and cost-of-living allowance adjustments in order to partially fund retiree health care benefits, if the parties' settlement is approved. (Docket No. 879, Ex. 1, MOU at 6; *see also* Docket No. 24, Ex. 1, Proposed Settlement Agreement § 13.B)

48. The MOU provides that "Future Retirees," defined as hourly Ford employees retiring after December 22, 2005, will receive retiree health care benefits pursuant to the terms of the Settlement Agreement on the same basis as class members, although Future Retirees are not class members. (Docket No. 879, Ex. 1, MOU at 4, 7)

I. The Proposed Settlement

49. The parties' Settlement provides for the establishment of a new health care plan, called the "Modified Plan," and the establishment of the DC-VEBA.

50. Ford/UAW retirees currently pay no monthly premiums or co-insurance and are not subject to any annual deductibles. For the most financially vulnerable retiree households, this remains unchanged. These "Protected Retirees" will continue to pay no monthly premiums or yearly deductibles. This protected category includes approximately 32,000 class members, or almost 20% of the class (Docket No. 24, Jt. Mot. For Prelim. Approval at 9), and consists of class members who (a) are entitled to an annual Ford pension benefit income of \$8,000 or less;

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and (b) receive a pension based on a monthly rate of \$33.33 or less per year of credited service. (Docket No. 24, Ex. 1, Proposed Settlement Agreement ¶ 7) Protected Retirees will see only minor administrative modifications to their benefits. (*See id.* at 13-14) Only two of the seven class representatives are “Protected Retirees.” (*See* Class Representatives’ Declarations, Docket Nos. 906, 908-12, 915).

51. Under the terms of the Settlement, remaining class members who participate in the regular Ford program, termed “General Retirees,” will pay modest new charges as part of the Modified Plan. In the initial plan year, taking into account mitigation provided by the DC-VEBA which is described *infra*, the impact on General Retirees will be as follows:

- Monthly premiums will be \$10 for individual participants and \$21 for family participant

*11 • Deductibles will be \$150 per individual participant, subject to an aggregate limit of \$300 per family; and

- “Co-insurance” will be instituted, meaning that General Retirees will be responsible for 10% of most medical charges. The effect of this new co-insurance will be minimal because a new “out-of-pocket” maximum will cap the annual total of deductibles and co-insurance at \$250 per single person and \$500 per family for in-network services.

(Docket No. 24, Ex. 1, Proposed Settlement Agreement § 14.A) At most, these new charges can cost a single retiree \$370 per year (\$120 in premiums, \$150 in a deductible, and another \$100 in co-insurance to reach the out-of-pocket maximum), and can cost a family \$752 per year (\$252 in premiums, \$300 in a deductible, and another \$200 in co-insurance to reach the out-of-pocket maximum) for in-network services. (Docket No. 878, Ex. 1, Payne Dec. ¶ 33) Based on their pensions, five of the seven class representatives would be “General Retirees.” (*See* Class Representatives’ Declarations, Docket Nos. 906, 908-12, 915)

52. Under the Modified Plan, General Retirees

will have prescription drug coverage under which they will be responsible for modest co-payments. For drugs purchased at retail, the co-payment is \$5 for generic drugs and \$12 for brand-name drugs. (Docket No. 24, Ex. 1, Proposed Settlement Agreement § 5.A.2(f))

53. General retirees will also be subject to a co-payment rate of \$50 per emergency room visit unless the patient is admitted, in which case the co-payment is waived. (Docket No. 24, Ex. 1, Proposed Settlement Agreement § 5.A.2(e))

54. All of these dollar denominated amounts are subject to annual increases of no more than three (3) percent. (*Id.* § 5.B)

55. Even with these increases, and assuming no mitigation, the Modified Plan provides a range of benefits for retirees that substantially exceeds the benefits generally available to most other retirees under health care plans offered by large U.S. employers, and at a cost to retirees that is substantially less than most other retirees pay. (Docket No. 882, Ex. E, Borzi Decl. ¶¶ 20-21) The Modified Plan is more generous as compared to other large employer-sponsored retiree health care plans with respect to monthly premiums, annual deductibles, out-of-pocket maximums, and prescription drug benefits. (*Id.*) Additionally, Ford has submitted an expert evaluation indicating that even as modified, its retiree health benefits remain among the most generous in the nation. (*See* Docket No. 882, Ex. E, Borzi Decl. ¶ 21)

56. Under the terms of the Settlement Agreement, Ford remains responsible for providing retiree health care coverage. Funds in the DC-VEBA will be used to mitigate the monthly contributions, deductibles, out-of-pocket maximums, and/or co-insurance amounts payable by retirees; dental benefits also will be paid out of the DC-VEBA. (Docket No. 24, Ex. 1, Proposed Settlement Agreement § 14.A)

*12 57. Under the Settlement Agreement, retirees who do not enroll in the Modified Plan will be enrolled in the Catastrophic Plan. The Catastrophic Plan does not require any monthly

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premiums, but it has, *inter alia*, higher deductibles and higher co-payments for emergency room visits and for prescription drugs, and no dental coverage. (*Id.* § 6 & Ex. 2)

58. Under the Settlement Agreement, the parties will establish the DC-VEBA, which will be governed by a board of trustees entirely independent of Ford. The DC-VEBA is designed to reduce costs for health care benefits, that, under the Settlement Agreement, will not be paid by Ford. (*See id.* § 14) This trust will be funded from several sources. Ford will contribute \$108 million to the DC-VEBA in the form of contributions of \$30 million in 2006, \$35 million in 2009, and \$43 million in 2011. (*Id.* § 13.A) The 2009 and 2011 contributions will be made earlier if the balance of funds in the trust falls below a level sufficient to provide the cost mitigation described above. (*Id.*)

59. Active UAW-represented employees will contribute to the DC-VEBA through the deferral of an average of 99 cents per hour of future wage increases, consisting of (i) a total of \$0.17 per hour of cost of living adjustments at a maximum rate of \$0.06 per quarter, and (ii) the scheduled September 2006, 3% wage increase. In addition, active hourly employees will defer \$0.02 per hour of cost of living increases cumulatively in each subsequent quarter. (*Id.* § 13.B) All told, each active UAW-represented employee initially will give up approximately \$2,000 per year in order to fund the DC-VEBA for the benefit of retirees, and this amount will increase each year. (Docket No. 896, Bantom Decl. ¶¶ 36-37)

60. The DC-VEBA will also hold stock appreciation rights on 8,750,000 shares of Ford stock. Ford will be required to make additional deposits to the DC-VEBA based on future increases in Ford's stock price. (*Id.* § 13.C) The DC-VEBA will also receive an additional payment in the event Ford issues any special dividends between December 14, 2005 and the third anniversary of the Effective Date of the Settlement Agreement. (*Id.* § 13.D)

61. The Settlement Agreement will continue in effect until at least September 14, 2011. (*Id.* §

18) Thereafter, the Settlement Agreement will continue in effect indefinitely, unless either Ford or the UAW elects to terminate it. (*Id.*)

62. In the event that Ford or the UAW elects to terminate the Settlement Agreement, it provides that all parties will remain protected by the "No Admissions; No Prejudice" provisions set forth in Section 19 of the Agreement. (*Id.*) In the event of such termination, the class will be free to sue not only to reinstate the benefits of the Modified Plan, but also to prospectively reinstate the current plan, *i.e.*, a comprehensive plan without monthly contributions and deductibles. (*See id.*) Also in the event of such termination and ensuing litigation, the applicable body of decisional law will be case law as of the date the Settlement goes into effect. *E.g.*,  *UAW v. Yard-Man, Inc.*, 716 F.2d 1476 (6th Cir.1983). (Docket No. 24, Ex. 1, Proposed Settlement Agreement § 19)

*13 63. The Settlement Agreement provides that the Court's final judgment will expressly recite and confirm the provisions of Section 19, the "No Prejudice" provision. (*Id.* § 19) Those provisions are as follows:

No Admissions; No Prejudice

A. Notwithstanding anything to the contrary, whether set forth in this Settlement Agreement, the MOU, the Judgment, the Notice Order, any documents filed with the Court in the Hardwick Case, any documents whether provided in the course of or in any manner whatsoever relating to the 2005 and 2006 discussions between Ford and UAW and Class Counsel with respect to health care benefits or relating to this Settlement Agreement or the MOU, whether distributed, otherwise made available to or obtained by any person or organization, including without limit, Active Employees, Class Members, or the spouses, surviving spouses or dependants of any of the foregoing, or to the UAW or Ford in the course of the negotiations that led to entry into this Settlement Agreement, or otherwise:

(a) Ford denies and continues to deny any wrongdoing or legal liability arising out of any of

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the allegations, claims and contentions made against Ford in the Hardwick Case and in the course of the negotiation of the MOU or this Settlement Agreement. None of the MOU, any disputes or discussions between Ford and the UAW with respect to health care benefits or regarding entry into this Settlement Agreement occurring on or after January 1, 2005, this Settlement Agreement nor any document referred to or contemplated herein nor any action taken to carry out this Settlement Agreement nor any retiree health care benefits provided hereunder or any action related in any way to the ongoing administration of such retiree health care benefits (collectively, the "*Settlement Actions*") is, may be construed as, or may be viewed or used as, an Admission by or against Ford of any fault, wrongdoing or liability whatsoever, or as an Admission by Ford of the validity of any claim or argument made by or on behalf of the UAW, Active Employees, the Class or Future Retirees, that retiree health benefits are vested. Without limiting in any manner whatsoever the generality of the foregoing, the performance of any Settlement Actions by Ford may not be construed, viewed or used as an Admission by or against Ford that, in the event of the termination of this Settlement Agreement pursuant to Section 18, it does not have the unilateral right to modify or terminate retiree health care benefits.

(b) Each of the UAW, the Class Representatives and the Class Members claim and continue to claim that the allegations, claims and contentions made against Ford in the Hardwick Case have merit. Neither this Settlement Agreement nor any document referred to or contemplated herein nor any Settlement Actions may be construed as, or may be viewed or used as, an Admission by or against any of the UAW, the Class Representatives or the Class Members of any fault, wrongdoing or liability whatsoever or as an Admission by the UAW, the Class Representatives or the Class Members of the validity of any claim or argument made by or on behalf of Ford that Ford has a unilateral right to modify or terminate retiree health care benefits or that retiree health care benefits are not vested. Without limiting in any manner whatsoever the generality of the foregoing, the performance of any Settlement Actions by any of the UAW, the Class Representatives or the Class Members,

including without limitation, the acceptance of any retiree health care benefits under any of the Ford health care plans set forth in this Settlement Agreement, may not be construed, viewed or used as an Admission by or against any of the UAW, the Class Representatives or the Class Members that, in the event of the termination of this Settlement Agreement pursuant to Section 18, Ford has the unilateral right to modify or terminate retiree health care benefits.

*14 (c) There has been no determination by any court as to the factual allegations made against Ford in the Hardwick Case. Entering into this Settlement Agreement and performance of any of the Settlement Actions shall not be construed as, or deemed to be evidence of, an Admission by any of the parties hereto, and shall not be offered or received in evidence in any action or proceeding against any party hereto in any court, administrative agency or other tribunal or forum for any purpose whatsoever other than to enforce the provisions of this Settlement Agreement or to obtain or seek approval of this Settlement Agreement in accordance with  Rule 23 of the Federal Rules of Civil Procedure and the Class Action Fairness Act of 2005.

For the purposes of Section 19 of this Settlement Agreement, Ford and the UAW refer to Ford Motor Company and the Union, respectively, as organizations, as well as any and all of their respective directors, officers, and agents.

B. (a) This Settlement Agreement and anything occurring in connection with reaching this Settlement Agreement are without prejudice to Ford, the UAW and the Class Members. The parties may use this Settlement Agreement to assist in securing the Judgment approving the settlement and to implement the Administrative Changes, Modified Plan, Catastrophic Plan, and DC VEBA in accordance with the Exhibits to this Settlement Agreement. It is intended that neither Ford nor the UAW, Future Retirees or the Class Members may use this Settlement Agreement, or anything occurring in connection with reaching this Agreement, as evidence against Ford, the UAW or the Class Members in any circumstance except where the parties are operating under or enforcing this Settlement Agreement or the Judgment approving this Settlement Agreement.

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(b) Ford, the UAW, and the Class Members expressly agree and acknowledge that each party is entering into this Settlement Agreement and compromising material claims in light of the Case Law as it exists as of the Effective Date. For purposes of this Settlement Agreement, "Case Law" shall mean, judicial decisional law, whether existing in the federal system (including, but not limited to, decisions of the United States Supreme Court or any United States Circuit Court of Appeals) or in any state or locality; but does not include statutes, regulations, codes, rules or subsequent legislative, regulatory or administrative developments.

Each of the parties hereto further expressly agree and acknowledge that in the event that Ford terminates this Settlement Agreement following the Effective Date in accordance with Section 18 hereof, and there is litigation between Ford, the UAW and/or, the Class Members over the right of Ford to unilaterally modify and/or terminate retiree health benefits or whether such benefits are vested, the Case Law as of the Effective Date shall be treated as the applicable body of judicial decisional law for such litigation, subject to any and all changes in the applicable law from legislative, regulatory, or administrative developments after the Effective Date and provided that neither the Class Members nor the UAW would retain the right to seek, damages, reimbursement, recovery or equitable relief in connection with the health care changes incorporated in this Settlement Agreement and the applicable plans for the Effective Period. Moreover, (i) Ford, the UAW, and the Class Members may make any and all arguments in any such litigation as are available to them regarding such Case Law as of the Effective Date and (ii) for purposes of any applicable statute of limitations in such litigation, any changes in retiree health care benefits provided for in this Settlement Agreement shall be deemed to have occurred on the date this Settlement Agreement terminates.

*15 For the avoidance of doubt, it is the express intention and agreement of Ford, the UAW and Class Members to apply the Case Law as it exists as of the Effective Date to any litigation between Ford, the UAW, and/or Class Members over the right of Ford to unilaterally modify and/or terminate retiree health benefits or whether such benefits are vested should this Settlement Agreement be terminated by Ford following the Effective Date in accordance with

Section 18, subject to any and all changes in the applicable law from subsequent legislative, regulatory, or administrative developments and the right of Ford, the UAW and the Class Members to make any and all arguments in any such litigation as are available to it regarding such Case Law as of the Effective Date. No judicial decisions issued after the Effective Date shall be relevant to or have any bearing on consideration or resolution by any court, administrative agency or other tribunal or forum of the issue of Ford's right to unilaterally modify and/or terminate retiree health care benefits or whether such benefits are vested in any litigation between Ford, the UAW, and/or Class Members should this Settlement Agreement be terminated by Ford in accordance with Section 18, except insofar as such judicial decisions interpret, apply, or reflect changes in applicable law resulting from legislative, regulatory or administrative developments after the Effective Date. Ford, the UAW and/or Class Members shall not be precluded from raising any legal theory or argument which such parties could have made under the Case Law as of the Effective Date merely because it is reflected in a judicial decision after the Effective Date.

This provision is a material part of this Settlement Agreement. The Judgment shall expressly recite and confirm the provisions of this Section 19. In the event this Settlement Agreement is terminated, nothing in Section 19 shall prevent Ford, the UAW, and the Class Members from using, relying or referring, in support of their respective positions, to any documentary evidence which was in existence on January 1, 2005, and which such parties, on the Effective Date, could have used, relied upon or referred to in support of their respective positions, except that plan documents and similar material prepared and distributed up to the Ratification Date without regard to the discussions leading up to the negotiation of the MOU and this Settlement Agreement may be so relied upon and referred to by Ford, the UAW or Class Members, to the extent such documents and similar materials are consistent with the previous versions that were in effect on January 1, 2005.

Ford further agrees, in its capacity as settlor, sole sponsor and administrator of Ford's H-S-M-D-D-V Program, that such Program shall, to the extent permitted by ERISA, be bound by Section 19 to the same extent as Ford and is subject to the same

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conditions and limitations as Ford under this Section.

64. With regard to counsel fees and expenses, the Settlement Agreement provides that Ford will support application by the UAW and Class Counsel for reimbursement by Ford of reasonable attorney and professional fees and expenses for hours worked in an amount to be determined in accordance with current market rates (not to include arrangements such as any contingency fees, success fee, completion bonus, or rate premiums) incurred in connection with the court proceedings to obtain the judgment approving the Settlement Agreement. (Docket No. 24, Ex. 1, Proposed Settlement Agreement § 20 .B) The Settlement Agreement provides that approval of these fee requests will be included in the Court's judgment. (*Id.*)

J. The Parties' Conclusions Regarding Settlement

*16 65. Based on their investigation, Class Counsel determined, on behalf of the class, that it is in the best interest of the class that this case be settled as set forth in the Settlement Agreement, and that the terms of this Settlement are fair and reasonable. (Docket No. 24, Ex. 1, Proposed Settlement Agreement § 4)

66. The UAW has also concluded that the Settlement is fair, reasonable, and in the best interests of the class. (*Id.*).

67. Ford has concluded that it is desirable, beneficial, and in the company's best interests that the claims of class members are settled as set forth in the Settlement Agreement and that the terms of the Settlement are fair and reasonable. (*Id.*)

68. The class, the UAW, and Ford have all concluded that approval of the Settlement will confer a significant public benefit. (*Id.*)

K. Objections

69. Out of the approximately 170,000 class members

who were sent notice, there were a total of 794 objections, not counting (i) duplicate objections filed on behalf of the same individual, and (ii) objections that disclose on their face that the objector is not a member of the class. (*See Doc. 882, Ex. L, Young Decl. ¶ 3*) The objectors comprise only one half of one percent of the class of 170,000. Using this ratio, if the class had consisted of 5000 members, only 23 would have objected.

70. Of the objections filed, most (508) contained no statement of the reasons for the objection. (*Id. ¶ 5*)

71. Objectors who did give reasons raised several topics. In terms of objections relating directly to class claims and the substance of the Settlement Agreement, objectors have asserted that their benefits were promised and/or provided for in written documents and were vested or for life and could not be altered (*see, e.g.*, Doc. 70, 71), that Ford is not facing financial distress (*see, e.g.*, Doc. 166), that the changes to health care benefits applicable under the proposed settlement to retirees should also apply to active employees, or that the changes should apply only to active employees (*see, e.g.*, Doc. 97), that it was unfair that objectors could not vote to approve or disapprove of the Settlement (*see, e.g.*, Doc 49), that objectors were not properly represented by the UAW (*see, e.g.*, Doc. 55), that under the proposed changes, objectors would have difficulty affording their medical benefits (*see, e.g.*, Doc. 66), that class members age 65 and older should be exempt from the Settlement because Medicare picks up many of the costs for such members (*see, e.g.*, Doc. 166), that benefits should not be altered because retirees already paid into and/or worked to earn their benefits (*see, e.g.*, Doc. 55), that the DC-VEBA will go broke (*see, e.g.*, Doc. 141), and that the Class Notice was vague and/or difficult to understand. (*See, e.g.*, Doc. 88)

72. In terms of more general grievances, objectors have asserted that Ford's financial difficulties are the fault of Ford management, and that it is management, not retirees, or together with retirees, who should now make sacrifices (*see, e.g.*, Doc. 142), that they went on strike and/or made other sacrifices to obtain

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their benefits (*see, e.g.*, Doc. 86), that working at Ford caused their current health conditions (*see, e.g.*, Doc. 145), that they should be allowed to return to their former jobs at Ford (*see, e.g.*, Doc. 75), and that Ford misused their benefit money. (*See, e.g.*, Doc. 102, 113)

*17 73. Objectors also argue that various changes should be made to the proposed settlement. For example, a few objectors argue that the group of protected retirees should be expanded, either by increasing the \$8,000 ceiling (*see, e.g.*, Doc. 145) or by including disabled retirees. (*See, e.g.*, Doc. 362, 392) On the other hand, at least one objector complains that the protected class of retirees should not exist at all because they will not share in the additional costs of benefits. (*See, e.g.*, Doc. 584) Another objector has argued that the costs to retirees should be graduated based on their pension amounts. (*See, e.g.*, Doc. 396) At least one objector contends that the monthly premium should be eliminated and retirees should only pay per usage. (*See, e.g.*, Doc. 97) At least one objector argues that special costs should be set for retirees who worked at Ford for less than 30 years. (*See, e.g.*, Doc. 469) And at least one objector argues that costs should only apply to those retirees who receive pension bonuses. (*See, e.g.*, Doc. 458)

74. One objector, Dennis Lapso, who is represented by counsel other than objectors counsel, asked the Court to defer ruling on the fairness of the Settlement until his internal appeal within the UAW was decided. (Doc. 390)

75. The “Bronson Group of Objectors,” referred to herein as “Bronson,” make several objections. First, Bronson asserts that the class did not receive adequate representation. (Doc. 739, Objection at 12-27) Specifically, Bronson contends that the UAW had a conflict of interest; that Class Counsel are inadequate because they did not negotiate a more favorable settlement and allegedly failed to conduct an independent investigation into the fairness of the settlement; and that the class representatives are inadequate. Bronson also argues that class treatment is “problematic” under the Due Process Clause and the Seventh Amendment.

(*Id.* at 27-29)

76. Bronson also makes several arguments in an attempt to establish that the Settlement is not fair, reasonable, and adequate. (*Id.* at 29-38) Bronson contends that the Settlement allegedly was not the product of arm’s length negotiations. He also asserts that the Settlement places an unfair burden on retirees relative to current Ford employees. In addition, he maintains that what he believes is the strong likelihood of plaintiffs’ success on the merits “weighs against” approval of the settlement.

77. Finally, Bronson asserts that the notice sent to class members was inadequate and that the settlement violates the Age Discrimination in Employment Act. (*Id.* at 38-41)

L. General Findings

78. The Court finds that there is no evidence supporting a conclusion or an inference that there was any improper collusion among or between any of the parties to this litigation. To the contrary, the above cited record evidence, and in particular the evidence surrounding the negotiation of the Settlement Agreement, establishes that the parties’ conduct in connection with this litigation was at all times above-board and non-collusive.

*18 79. The above-cited record evidence establishes that Class Counsel diligently investigated the proposed Settlement, acted solely in the interest of the class, and concluded, based upon the expert opinions and their considerable experience in like cases, that the Settlement is fair, reasonable, and adequate.

80. The Court finds that there is no evidence supporting a conclusion or an inference that the UAW was improperly motivated to preserve active employees’ interests at the expense of retiree medical benefits. To the contrary, the evidence amply supports a finding that the UAW negotiated the Settlement in good faith and for the purpose of furthering the strong mutual interest of active and retired employees in keeping Ford in business, enabling the

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company to continue to employ active employees and to continue to provide quality benefits to retirees.

81. The record evidence establishes that this case does not involve a limited fund, an artificially created limited fund, or an externally limited pool of assets for satisfaction of competing claims. Nor does this case involve anything analogous to a limited fund in any form. To the contrary, the evidence establishes that a key objective of the Settlement is to address Ford's financial struggle and maintain the company's viability, allowing the continued generation of income from which both active employees and retired employees will benefit for the foreseeable future.

82. The Court finds that the cost increases entailed by the Settlement are modest, and the most financially vulnerable retirees will be protected from even those modest costs. The potential loss of all benefits, due to either Ford's financial difficulties or Ford's prevailing on the merits, would be far worse for all class members than the relatively modest charges they will be required to pay under the Settlement Agreement.

II. CONCLUSIONS OF LAW

A. Jurisdiction

1. This Court has jurisdiction under Section 301 of the LMRA, 29 U.S.C. § 185, and Section 502(e)(1) and (f) of ERISA, 29 U.S.C. § 1132(e)(1) and (f).

B. Class Certification

2. In order to be certified, the proposed class must meet the requirements of Rule 23(a), and one of the three subsections of Rule 23(b). *Sprague v. General Motors Corp.*, 133 F.3d 388, 397 (6th

Cir.1998) (en banc). When, as here, the case is settled before the class is certified, the requirements of Rule 23 that are designed to protect absent class members "demand undiluted, even heightened, attention." *Amchem Prods. v. Windsor*, 521 U.S. 591, 620, 117 S.Ct. 2231, 138 L.Ed.2d 689 (1997).

3. Following a meeting with the parties and counsel for Bronson objectors on February 24, 2006, the Court, per Judge Tarnow, concluded that the requirements of Rule 23(a) and Rule 23(b)(2) had been met, and certified the class. Based on the record as a whole, including evidence and written submissions received at and after the fairness hearing, the Court now confirms that the class is properly certified.

*19 i. Numerosity. There are more than 170,000 class members, which satisfies the requirement that the class is "so numerous that joinder of all members is impracticable." *FED. R. CIV. P. 23(a)(1)*. See, e.g., *Bittinger v. Tecumseh Prods. Co.*, 123 F.3d 877, 884 n. 1 (6th Cir.1997) (objection based on numerosity requirement was frivolous where class consisted of 1,000 members).

ii. Commonality. The requirement of commonality requires only a common question of law or fact. *Bittinger*, 123 F.3d at 884; see also *Sprague*, 133 F.3d at 397 (noting that one common question of law or fact is sufficient). Here, the question whether Ford has the right to unilaterally modify or terminate retiree health benefits is a question common to all class members. *Bittinger*, 123 F.3d at 879, 884 (commonality requirement met where retirees sought lifetime benefits, even though a series of different CBAs governed the benefits); *Fuller v. Fruehauf Trailer Corp.*, 168 F.R.D. 588, 596 (E.D.Mich.1996) (determination of effect of defendant's reservation of rights provides common question under Rule 23(a)(2)).

iii. Typicality. "A plaintiff's claim is typical [under Rule 23(a)(3)] if it arises from the same event or practice or course of conduct that gives rise to the claims of other class members,

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and if his or her claims are based on the same legal theory.” *In re Am. Med. Sys.*, 75 F.3d 1069, 1082 (6th Cir.1996) (quotation and citation omitted). The requirement is not onerous. If there is a strong similarity of legal theories, the requirement is met, even if there are factual distinctions among named and absent class members. See *Bittinger*, 123 F.3d at 884-85; *Forbush v. J.C. Penny Co.*, 994 F.2d 1101, 1106 (5th Cir.1993).

4. The plaintiffs claim that Ford’s decision to unilaterally modify or terminate their retiree health benefits violates Ford’s obligations under ERISA and under the CBAs between Ford and UAW. Each plaintiff asserts an identical obligation by Ford and satisfies the typicality requirement, notwithstanding any purported factual differences with respect to individual class members. *Bittinger*, 123 F.3d at 884 (typicality satisfied where plaintiffs claimed that defendant had promised to provide lifetime, fully-funded benefits to retirees).

5. Adequacy of Class Representatives. To satisfy Rule 23(a)(4), class representatives “must possess the same interest and suffer the same injury.” *Amchem*, 521 U.S. at 625-26. The two criteria for determining whether class representatives are adequate are “(1) the representatives must have common interests with unnamed members of the class, and (2) it must appear that the representatives will vigorously prosecute the interests of the class through qualified counsel.” *Senter v. General Motors Corp.*, 532 F.2d 511, 525 (6th Cir.1976). Here, the class representatives share the same interest in protecting retiree health benefits, the record reflects that they have vigorously pursued that interest to date, and there is nothing to suggest that they would not vigorously protect the interests of the class.

***20** 6. Nor are there any intra-class conflicts that would defeat the adequacy requirement or class certification. “[O]nly a conflict that goes to the very subject matter of the [claims] will defeat a party’s claim to representative status. CHARLES ALAN WRIGHT, ET AL., FEDERAL PRACTICE AND PROCEDURE §

1768 (West 2005). “Differences between named plaintiffs and class members render the named plaintiffs inadequate representatives only if those differences create conflicts between the named plaintiffs’ interests and the class members’ interests.” *Mullen v. Treasure Chest Casino, LLC*, 186 F.3d 620, 625-26 (5th Cir.1999). See also *Steiner v. Equimark Corp.*, 96 F.R.D. 603, 610 (W.D.Pa.1983) (“key question” is whether named representatives’ interests are antagonistic to interests of class members).

7. The named representatives’ interests are not in conflict with or antagonistic to the interests of class members simply because the Settlement may impact individuals differently based on preexisting circumstances. See *Kamen v. Kemper Fin. Servs., Inc.*, 908 F.2d 1338, 1350 (7th Cir.1990) (differences among class members should be distinguished from a “concrete conflict of interest between ‘representative’ and other members of the class”), *rev’d on other grounds*, 500 U.S. 90, 111 S.Ct. 1711, 114 L.Ed.2d 152 (1991); *Halford v. Goodyear Tire & Rubber Co.*, 161 F.R.D. 13, 20 (W.D.N.Y.1995) (no antagonism among class members where claims sought injunction seeking reinstatement of retiree benefits). “If subclassing is required for each material legal or economic difference that distinguishes class members, the Balkanization of the class action is threatened.” *In re Cendant Corp. Sec. Litig.*, 404 F.3d 173, 202 (3d Cir.2005) (noting that a “fragmented class might be unmanageable, would reduce the economic incentives [of class litigation] and could be extremely difficult to settle.”).

8. Adequacy of Class Counsel. To evaluate the adequacy of Class Counsel, Rule 23(g)(1)(i) requires the Court to consider (a) the work counsel has done in identifying or investigating potential claims in the action, (b) counsel’s experience in handling class actions, other complex litigation, and claims of the type asserted in the action, (c) counsel’s knowledge of the applicable law, and (d) the resources counsel will commit to representing the class.

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9. Class Counsel in this case is adequate and has the resources to commit to representing the class. The evidence established that Class Counsel is well-qualified, has extensive knowledge of the law relating to retiree benefits litigation, and has substantial experience litigating actions of this kind.

10. The Court also concludes that the class may be certified under Rule 23(b)(2). A class is properly certified under Rule 23(b)(2) if “the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole.”

FED. R. CIV. P. 23(b)(2). Certification under Rule 23(b)(2) is appropriate when “the common claim is susceptible to a single proof and subject to a single injunctive remedy.” Senter, 532 F.2d at 525. That is the case here, where plaintiffs challenge Ford’s decision to modify retiree health benefits. See, e.g. *id.*; Forbush, 994 F.2d at 1106.

*21 Accordingly, the Court GRANTS final certification of the Class defined above in the Findings of Fact.

C. Final Approval of the Class Action Settlement

11. To ensure that the interests of class members are protected, Rule 23(e)(1)(C) requires the Court to hold a hearing to determine whether the settlement is a “fair, reasonable, and adequate” resolution of class members’ claims. That Fairness Hearing was held on May 31, 2006.

12. The law favors the voluntary settlement of class action litigation. Steiner v. Fruehauf Corp., 121 F.R.D. 304, 305 (E.D.Mich.1988), aff’d sub nom. Priddy v. Edelman, 883 F.2d 438 (6th Cir.1989).

13. Given this policy, in reviewing a class action settlement, the role of the district court is “limited to a determination of whether the terms proposed are fair and reasonable to those

affected .” Steiner, 121 F.R.D. at 305. Settlement embodies “a bargained give and take between the litigants that is presumptively valid,” Berry, 184 F.R.D. at 97, about which “the Court should not substitute its judgment for that of the parties.” Steiner, 121 F.R.D. at 306. Further, the Court should not decide the merits of the dispute. See Clark Equip. Co., 803 F.2d at 880. Nor should the Court engage in the “detailed and thorough investigation that it would undertake if it were actually trying the case,” Berry, 184 F.R.D. at 98 (quoting Armstrong v. Bd. Of Sch. Directors, 616 F.2d 305, 315 (7th Cir.1980)), because the “whole purpose behind a compromise is to avoid a trial.” Charles A. Wright et al., Fed Prac. & Proc. § 1797.5.

14. “In assessing the settlement, the Court must determine ‘whether it falls within the range of reasonableness, not whether it is the most favorable possible result in the litigation.’ ”

In re Domestic Air Transp. Antitrust Litig., 148 F.R.D. 297, 319 (N.D.Ga.1993) (quoting Fisher Bros. v. Cambridge-Lee Indus., 630 F.Supp. 482, 489 (E.D.Pa.1985)). An appropriate range of reasonableness “recognizes the uncertainties of law and fact in any particular case and the concomitant risks and costs necessarily inherent in taking any litigation to completion.” Frank v. Eastman Kodak Co., 228 F.R.D. 174, 186 (W.D.N.Y.2005) (quoting Newman v. Stein, 464 F.2d 689, 693 (2d Cir.1972)). Under this standard, “[a] just result is often no more than an arbitrary point between competing notions of reasonableness.” In re Corrugated Container Antitrust Litig. (II), 659 F.2d 1322, 1325 (5th Cir.1981).

15. Approval of a class action settlement is committed to the discretion of the district court. Clark Equip. Co., 803 F.2d at 880; Detroit Police Officers Ass’n v. Young, 920 F.Supp. 755, 761 (E.D.Mich.1995). In exercising that discretion, the Court “may limit the fairness hearing ‘to whatever is necessary to aid it in reaching an informed, just and reasoned decision.’ ” Tenn. Ass’n of Health Maint. Orgs., Inc. v. Grier, 262 F.3d 559, 567 (6th

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Cir.2001) (quoting *United States v. Oregon*, 913 F.2d 576, 582 (9th Cir.1990)). The Court may consider briefs, declarations, and the arguments of counsel, and need not conduct an evidentiary hearing. E.g., *Tenn. Ass'n of Health Maint. Orgs., Inc.*, 262 F.3d at 567 (rejecting the suggestion that “the fairness hearing must entail the entire panoply of protections afforded by a full-blown trial on the merits”); *Depoister v. Mary M. Holloway Found.*, 36 F.3d 582, 586 (7th Cir.1994) (“there is no requirement that an evidentiary hearing be conducted as a precondition to approving a settlement in a class action suit”). “Even when the Court becomes aware of one or more objecting parties, the Court ... may limit its proceeding to whatever is necessary to aid it in reaching an informed, just and reasoned decision.” *Ass'n for Disabled Americans, Inc. v. Amoco Oil Co.*, 211 F.R.D. 457, 467 (S.D.Fla.2002) (quoting *Cotton v. Hinton*, 559 F.2d 1326, 1331 (5th Cir.1977)). In other words, “the settlement or fairness hearing is not to be turned into a trial or rehearsal for trial on the merits.” *Officers for Justice v. Civil Serv. Comm'n*, 688 F.2d 615, 625 (9th Cir.1982). See also *In re Inter-Op Hip Prosthesis Liab. Litig.*, 204 F.R.D. 330, 350 (N.D.Ohio 2001) (same).

***22** 16. Factors relevant to the Court’s evaluation of the fairness of the Settlement are:

- (a) “the likelihood of success on the merits weighed against the amount and form of the relief offered in the settlement;
- (b) the risks, expense, and delay of further litigation;
- (c) the judgment of experienced counsel who have competently evaluated the strength of their proofs;
- (d) the amount of discovery completed and the character of the evidence uncovered;
- (e) whether the settlement is fair to the unnamed class members;
- (f) objections raised by class members;

(g) whether the settlement is the product of arm’s length negotiations as opposed to collusive bargaining; and

(h) whether the settlement is consistent with the public interest.”

In re Cardizem Antitrust Litig., 218 F.R.D. 508, 522 (E.D.Mich.2003)

17. The Court may choose to consider only those factors that are relevant to the settlement at hand and may weigh particular factors according to the demands of the case. *Granada Invest. Inc.*, 962 F.2d at 1205-06.

i. The likelihood of success on the merits weighed against the amount and form of the relief offered in the settlement

18. The legal issue presented in this case is whether plaintiffs’ retiree health benefits are vested. The parties vigorously dispute this issue, with class representatives and UAW on one side and Ford on the other side, asserting that governing Sixth Circuit law supports their respective positions. See, e.g., *Yolton v. El Paso Tenn. Pipeline Co.*, 435 F.3d 571, 572 (6th Cir.2006).

19. The parties make various legal and factual arguments in support of their positions, demonstrating the strongly contested nature of their dispute. The Court need not, and should not, resolve that dispute. *Clark Equip. Co.*, 803 F.2d at 880. The relevant question is whether the parties have been able to assess their respective positions and make an informed and appropriate determination about the relative merits and risks of settlement. The parties’ briefs and argument make clear that they have analyzed the relevant plan documents, understand the governing law, and have thoroughly evaluated the respective arguments on the merits.

20. Of equal importance, the parties recognize that, whatever the strengths of their positions, continued litigation involves substantial risks to each side. The parties acknowledge the inherent

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risks of litigation and the potentially catastrophic consequences for the retirees should the Court hold that their benefits are not vested. In that case, Ford would be able to institute changes in retiree health benefits significantly more costly to retirees or terminate the benefits altogether. Class representatives and the UAW reasonably concluded that even if their risk of losing was small, the consequence of a loss would be potentially calamitous for the UAW and the class. For the class, even a slight risk of substantially higher costs is well averted. *UAW v. GM*, 2006 WL 891151 at *16 (E.D.Mich. Mar.31, 2006). Thus, “[t]he fact that the plaintiff might have received more if the case had been fully litigated is no reason not to approve the settlement.”  *Priddy*, 883 F.2d at 447.

*23 21. It was reasonable for the plaintiffs to conclude that, considering Ford’s financial condition, the interests of the class lay not in achieving a possibly hollow victory in court but in continuing to receive their health benefits, and that the best means to do that lay in making modest concessions in settlement now in order to increase the likelihood that Ford will continue to be able to provide retiree health benefits into the future. *In re Milken and Assoc. Sec. Litig.*, 150 F.R.D. 46, 55-56 (S.D.N.Y.1993) (noting that continued litigation could impair defendant’s ability to pay).

22. Therefore, the Court concludes that the parties adequately assessed their respective positions on the merits. This is particularly so considering the realities of Ford’s financial position and the potential for catastrophic consequences to the class of a loss, no matter how small the risk.

23. Courts recognize that settlements are not crafted to secure the full value of the loss claimed by plaintiffs. “There is no reason, at least in theory, why a satisfactory settlement could not amount to a hundredth or even a thousandth part of a single percent of the potential recovery.” *Grinnell Corp.*, 495 F.2d at 455 n. 2.

24. Here, the Settlement Agreement provides considerable benefits to the class. (See Docket

No. 896, Taranto Decl. ¶ 8) (Modified Plan equals 87% of the value of current health benefits) Ford maintains responsibility for most of the cost of the Modified Plan. It realizes significant cost savings, without which Ford’s continued ability to provide benefits would be threatened, while maintaining a comprehensive level of coverage for class members with only a slight increase in cost. In fact, benefits will be maintained without a cost increase for the most financially vulnerable members of the class. (See Docket No. 24, Ex. 1, Proposed Settlement Agreement § 7) For other class members, with the partial mitigation funding provided by the DC-VEBA, a single participant’s monthly premium contribution initially will be \$10, with a 10% copay (after an annual deductible of \$150) up to a maximum out-of-pocket contribution of \$250. (*Id.* § 14.A) For a single retiree, these new charges can initially cost no more than \$370 per year—or just over one dollar per day. The co-payment for generic prescription drugs purchased at retail remains the same as the current plan (\$5.00) and for generic mail order prescriptions, the co-pay increases by only \$5.00 for a 90-day supply—or an additional \$1.67/month. (*Id.* § 5.A.2(f)) All of these cost increases are moderate, particularly compared to the costs faced by many employees and retirees in today’s economy. (Docket No. 882, Borzi Decl. ¶ 21.)

25. “As is true in any case, the proposed Settlement ‘represents a compromise in which the highest hopes for recovery are yielded in exchange for certainty and resolution.’” *In re Rent-Way*, 305 F.Supp.2d at 509 (citation omitted). Hence, whether the plaintiffs conceivably “might have received more if the case had been fully litigated” is not the issue.

 *Priddy*, 883 F.2d at 447. “It is neither required, nor is it possible for a court to determine that the settlement is the fairest possible resolution of the claims of every individual class member; rather, the settlement, *taken as a whole*, must be fair, adequate and reasonable.” *Shy v. Navistar Int’l Corp.*, 1993 WL 1318607, at *2 (S.D.Ohio May 27, 1993) (unpublished) (citing *Clark Equip. Co.*, 803 F.2d 878) (emphasis in original).

*24 26. The Court concludes that the benefits

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provided to the class under the Settlement are fair, reasonable, and adequate when weighed against the uncertainties of litigation and the risks posed by further erosion of Ford's financial condition.

ii. The risks, expense and delay of further litigation

27. In addition to the risk of losing, the litigation itself may impair the plaintiffs' prospects for obtaining the benefits they seek to protect. The parties agree that without a significant reduction in the costs of retiree health care, Ford's financial condition will continue to deteriorate.

28. Given the financial crisis facing Ford, the severe financial drag of its existing benefits liability, and the grave significance of these matters for class members, a prompt settlement is superior to continued litigation. See Christine Tierney & Brett Clanton, *Outlook! GM Rises, Ford Falls*, DET. NEWS, May 26, 2006, at A1, A9; see, e.g., *In re Milken*, 150 F.R.D. at 55-56 (S.D.N.Y.1993) (noting danger that prolonged litigation could impair defendant's ability to pay). The costs of litigation and the delay in effecting necessary cost-saving measures could lead to further deterioration of Ford's financial condition, which counsels in favor of settlement. See, e.g., *Godshall v. Franklin Mint Co.*, 2004 WL 2745890, at 5 (E.D.Pa. Dec.1, 2004). Even if plaintiffs ultimately prevailed, a court order confirming the vested nature of the retiree health benefits would be of little value if that order were directed to a corporation that could not survive in a form that would allow it to continue to provide such retiree health benefits over the long term.

29. The risk of huge expense and long delay is significant here. Litigation over retiree benefits is frequently costly and time-consuming, as demonstrated by other retiree health cases in this circuit. In *Sprague*, for example, GM salaried workers and retirees sued in 1989 challenging GM's modification of their health care benefits. Ultimately GM won, but only after nine years of litigation, including a trial in the district court and hearing (and rehearing) in

the Sixth Circuit. See *Sprague v. General Motors Corp.*, 133 F.3d 388 (6th Cir.1998) (en banc). Likewise, the litigation in *Bittinger v. Tecumseh Products* consumed eight years before it was finally resolved in favor of the employer on its second appeal to the Sixth Circuit. See 201 F.3d 440 (6th Cir.1999) (per curiam), aff'd 83 F.Supp.2d 851 (E.D.Mich.1999). The costs and uncertainty of lengthy and complex litigation weigh in favor of settlement. See *In re Cincinnati Policing*, 209 F.R.D. at 400 ("the Court has no doubt that the trial of this class action would be a long, arduous process requiring great expenditures of time and money on behalf of both the parties and the court [which] clearly counsels in favor of settlement.") (internal quotation marks and citations omitted).

30. At the Fairness Hearing, the Bronson objectors argued that retiree medical cases "go through quickly." (Docket No. 905, Tr. at 72-73) Mr. Baumkel argued that *Yolton v. El Paso TN. Pipeline Co.*, 435 F.3d 571 (6th Cir.2006), was decided "summarily" in favor of retirees after only two years of litigation. (*Id.* at 71-72) The Court of Appeals opinion in *Yolton*, however, reveals that the 2006 decision was merely the affirmance of a preliminary injunction based on a finding of "likely" success, not a final ruling, 435 F.3d at 578, and that litigation continues. The same is true of *Cole v. ArvinMeritor, Inc.*, 2005 WL 3502182 (E.D.Mich.2005) (granting preliminary injunction).

*25 31. In short, success at litigation (for either side) may prove illusory-a prospect that makes settlement an even more reasonable course. See, e.g., *In re Milken*, 150 F.R.D. at 66 (noting danger that prolonged litigation could impair defendant's ability to pay);

iii. The judgment of experienced counsel who have competently evaluated the strength of their proofs

32. "It is well recognized that the [C]ourt should defer to the judgment of experienced counsel who

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has competently evaluated the strength of the proofs.” *Mich. Hosp. Ass’n v. Babcock*, 1991 U.S. Dist. LEXIS 2058, at *6 (W.D.Mich. Feb. 11, 1991) (unpublished).

33. Here, counsel for all parties are reputable practitioners and trial counsel experienced in complex class action litigation. Under the law, their collective judgment in favor of the Settlement is entitled to considerable weight. *Ass’n for Disabled Americans, Inc.*, 211 F.R.D. at 467 (“the Court must rely upon the judgment of experienced counsel and, absent fraud, should be hesitant to substitute its own judgment for that of counsel.”) (citation and quotation omitted).

class and the UAW of Ford’s business and financial condition, including its health care liability, and the relevant CBAs and health care plan documents. This is confirmed by both the UAW and the class, who selected experts and undertook their own independent analyses of Ford’s condition. The Court concludes that there was significant information available to the parties to negotiate their compromise, and there is more than an adequate basis and record on which the Court can assess the parties’ agreement. It also is noteworthy that all of the Ford financial information as well as the CBA’s and plan documents-all of the information provided by Ford to UAW and Class Counsel-was also produced to counsel for Objector Bronson.

iv. The amount of discovery completed and the character of the evidence uncovered

34. In evaluating a proposed settlement, the Court need not possess sufficient “evidence to decide the merits of the issue, because the compromise is proposed in order to avoid further litigation.” 4 *Newberg on Class Actions* § 11:45 (4th ed.2002). Instead, the district judge need only have “sufficient facts before him to intelligently approve or disapprove the settlement.” *Epstein v. Wittig*, 2005 WL 3276390, at *7 (D.Kan. December 02, 2005) (unpublished).

35. In this regard, the absence of formal discovery is not an obstacle, so long as the parties and the Court have adequate information in order to evaluate the relative positions of the parties. See  *Newby v. Enron Corp.*, 394 F.3d 296, 306 (5th Cir.2004) (“[F]ormal discovery [is not] a necessary ticket to the bargaining table.”);  *Cotton*, 559 F.2d at 1332 (upholding settlement despite fact that little formal discovery had been conducted; “[B]eing an extra judicial process, informality in the discovery of information is desired.”); *Robinson v. Ford Motor Comp.*, 2005 U.S. Dist. LEXIS 11673, at *14-15 (S.D. Ohio June 15, 2005) (unpublished) (approving settlement without formal discovery).

36. Here, Ford provided full disclosure to the

v. Whether The Settlement Is The Product Of Arms-Length Negotiations As Opposed To Collusive Bargaining

*26 37. Courts presume the absence of fraud or collusion unless there is evidence to the contrary. *In re Rio Hair Naturalizer*, 1996 WL 780521, at *14 (“Courts respect the integrity of and presume good faith in the absence of fraud or collusion in settlement negotiations, unless someone offers evidence to the contrary.”). This presumption is conclusive here as no one has presented any evidence of collusion.

38. Here, there is a decidedly adversarial relationship between the class/UAW and Ford on the question of Ford’s right to unilaterally change, modify, or terminate health care benefits. Indeed, the parties are in fundamental disagreement on this issue. The Settlement was the result of protracted negotiations over several months, the exchange and evaluation of information, and the independent review and acceptance of the compromise by all parties. (Docket No. 24, Jt. Mot. For Prelim. Approval at 5-6) The settlement process was conducted wholly at arm’s length.

39. Many courts have held that if the settlement agreement itself is fair, reasonable and adequate, the Court may assume that the

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negotiations were proper and free of collusion. *E.g.*, *Bowling v. Pfizer, Inc.*, 143 F.R.D. 141, 152 (S.D.Ohio 1992) (“In essence, under this test, if the terms of the proposed settlement are fair, then the court may assume the negotiations were proper.”), *citing* *In re Corrugated Container Antitrust Litig.*, 643 F.2d 195, 212 (5th Cir.1981) (“It is, ultimately, in the settlement terms that the class representatives’ judgment and the adequacy of their representation is either vindicated or found wanting.”).

40. In considering this factor, courts have also looked to whether (1) the named plaintiffs’ claims are treated more favorably than other plaintiffs’ claims, and (2) the fee agreement suggests collusion. See *Heit v. Van Ochten*, 126 F.Supp.2d 487, 490-91 (W.D.Mich.2001). Neither consideration raises concerns here. The class representatives obtain no different or more favorable treatment under the Settlement Agreement than any other class member. And Class Counsel’s fee petition, which is subject to court approval, makes clear that they seek fees from Ford based solely on hours worked at a reasonable rate, not a premium or contingency fee arrangement.

vi. Whether the settlement is fair to the unnamed class members

41. The class is cohesive and the Settlement Agreement affects similarly situated class members the same. No preference is granted to the class representatives and because all class members have a unitary interest in seeking the best possible benefits for retirees, there is no risk of an undue burden on absent class members. *See, e.g.*, *Heit*, 126 F.Supp.2d at 490-491.

vii. Whether the settlement is consistent with the public interest

42. There is no question that Ford’s continued

viability has a significant effect on the economy of Michigan, and indeed, the nation as a whole. The evidence established that approximately 131,000 Americans earn their livelihood building and selling Ford vehicles, and another 170,000 retired employees depend on Ford for their pensions. In 2005, Ford paid its 131,000 U.S.-based employees \$10.7 billion in wages and issued pension payments of \$2.9 billion to its more than 170,000 U.S. retirees. In Michigan alone, Ford is one of the largest employers, with over 62,000 residents on its payroll. Ford also purchases billions of dollars of automobile parts from manufacturers with a major presence in Michigan. In the past five years alone, Ford has purchased \$38 billion in parts and supplies in the United States. This substantial economic activity depends on Ford’s continued viability, which depends on managing the company’s huge health care costs.

*27 43. The delay and risks of litigation thus impact not only Ford, the UAW, and the class, but also the families, businesses, and communities that depend on Ford’s continued competitiveness and viability. Those interests are advanced by the Settlement. The Settlement also serves the public interest by conserving the resources of the parties and the Court and promoting the “strong public interest in encouraging settlement of complex litigation and class action suits.” *In re Cardizem*, 218 F.R.D. at 530.

D. Objections to the Settlement

44. “A court should not withhold approval of a settlement merely because some class members object.” *Mich. Hosp. Ass’n*, 1991 U.S. Dist. LEXIS 2058, at *10. On the other hand, although the Court must evaluate objections, it has an obligation to protect the interests of the “silent class majority,” even over “vociferous opposition by a vocal minority to the settlement.” *Mich. Hosp. Ass’n*, 1991 U.S. Dist. LEXIS 2058, at *10.

45. In this case, the minority was very small. Less than 800 out of more than 170,000 class members-less than one half of one percent-submitted an objection to the

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Settlement Agreement. This very small level of opposition is another reason to conclude that the Settlement is fair, reasonable, and adequate. *Robinson*, 2005 U.S. Dist. LEXIS 11673, at *17 (“a relatively small number of class members who object is an indication of a settlement’s fairness”) (citing *Newberg on Class Actions* § 11.48).

46. Of the small number of class members who objected, over half provided no basis for the objection. (See Docket No. 882, Ex. L ¶ 5.) General objections that provide no reason for the objection “carry little weight.”  *In re Rio Hair Naturalizer*, 1996 WL 780512, at *14;.

47. Of the objections that contain a statement concerning the basis for the objection, most objectors stated that they objected because they believe the Settlement is a breach of contract or promise, they had no vote on the Settlement, or they believe their benefits were vested. None of these objections provide a basis for withholding approval of the Settlement.

48. With respect to the objection that modification of retiree benefits is a breach of contract or that the benefits are vested, these objections amount to a disagreement over the merits of the parties’ dispute and are not a basis for disapproving the Settlement.  *Laskey v. Int'l Union, UAW*, 638 F.2d 954, 957 (6th Cir.1981) (“the objections made indicated these employees did not want to compromise at all but wanted full benefits, rather than making any complaint directed to the adequacy of their legal representation”).

49. Some objected that retirees were not allowed to “vote” on the Settlement. However, these objections are not addressed to the terms of the Settlement and misapprehend  Rule 23.  Rule 23 ensures fairness by the requirements for certification and by requiring the Court to make an independent determination that the Settlement is fair, reasonable, and adequate, not by taking a vote of class members.

*28 50. A number of objectors noted that they will experience hardship if the Settlement is

approved. However, much of the structure of the Settlement is aimed at mitigating the impact of premiums, deductibles, and the like on retirees and their families. The Settlement also protects the most vulnerable class members by continuing their comprehensive health benefits without imposing co-payments, co-insurance, or annual deductibles. Moreover, the Court cannot ignore that an unfavorable litigation outcome might result in even greater hardship to the risk of the class.

51. Other retirees objected because they felt that active employees and Ford’s management were unfairly asking retirees to accept cutbacks without shouldering their own fair share of the burden. (See, e.g., Docket No. 463) The evidence established, however, that the parties developed the Settlement in light of the relative burdens assumed by Ford, active workers and retiree class members. First, active Ford workers are giving up one-third of their scheduled wage increase (which will be compounded by future cost-of-living increases that will also be diverted into the DC-VEBA), which, at a total of approximately \$2,000 per active worker in the first year, represents a significant sacrifice. In addition, active workers will be subject to the same reduced health care benefits upon their retirement. (See Docket No. 896, Bantom Decl. ¶¶ 34-36) Second, Ford is taking other cost-saving measures including reducing its active hourly and salaried workforce and managerial staff. (See Docket No. 882, Ford Motor Corporation’s Brief in Support of Final Approval, at 8) Finally, before agreeing to the settlement, the UAW, based on advice from its financial advisor, concluded that because there are so many fewer active workers than retirees, spouses, surviving spouses, and retiree dependents (Docket No. 896, Bantom Decl. ¶ 26), active worker participation in the modified health plan would be less beneficial to retirees than the active workers’ contributions to the DC-VEBA. For these reasons, the Court concludes that this objection does not warrant disapproval.

i. Objections Submitted by Lawrence Bronson

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52. Objector Lawrence Bronson submitted a lengthy brief in support of his objections and a brief in response to the Settlement parties' motions for final approval, and his counsel provided argument at the Fairness Hearing. Among other things, Bronson objects to the adequacy of Class Counsel and the class representatives, and asserts that there is a conflict between UAW's interests in representing active workers and the interests of retiree class members. Second, Bronson objects because he claims that a mandatory Rule 23(b)(2) class violates the Due Process Clause and the Seventh Amendment. Third, he objects to specific terms of the Settlement and asserts that the Settlement is not fair, reasonable and adequate. And fourth, he objects that the class notice was insufficient. The Court has carefully considered Bronson's objections, and determined that they do not merit disapproval of the Settlement.

a. *Objection Concerning The Adequacy Of Class Counsel And The Class Representatives*

(a). *Objection concerning the role Of UAW in negotiating the settlement*

*29 53. Bronson argues that the Settlement must be tainted because the UAW has a "conflict of interest" between retirees and the active workers it represents.

He relies on *Allied Chemical Workers v. Pittsburgh Plate Glass Co.*, 404 U.S. 157, 174, 92 S.Ct. 383, 30 L.Ed.2d 341 (1971), but that decision does not establish an inherent conflict of interest. In *Pittsburgh Plate Glass* the Supreme Court held only that retirees were not "employees" within the meaning of the National Labor Relations Act, and that an employer therefore had no legal duty to bargain with the union over the benefits of workers who were already retired.

54. As for collective bargaining, the Supreme Court emphasized that a union could bargain on behalf of its retirees if the employer agreed. *Id.* at 181 n. 20. In fact, as Judge Cleland found in the *GM* case, "[t]he Sixth Circuit and other courts have since [*Pittsburgh Plate Glass*] held that a union may negotiate for, and assert rights

on behalf of, retirees." *UAW v. GM*, 2006 WL 891151, at *24 (citing *UAW v. Yard-Man, Inc.*, 716 F.2d at 1476 (6th Cir.1983)).

55. Bronson also relies on *Cleveland Electric Illuminating Co. v. Utility Workers*, 440 F.3d 809 (6th Cir.2006), for the proposition that a union lacks authority to negotiate on behalf of retirees. *Cleveland Electric*, contrary to Bronson's contention, explicitly holds that, under *Pittsburgh Plate Glass*, "a union and company may agree to bargain for retirees' benefits," and that "the union has standing to represent the retirees in any dispute concerning those benefits." *Id.* at 815. The Sixth Circuit added only that the union must obtain the retirees' consent in order to represent them in arbitrating a grievance over such benefits, *id.* at 817-18-a holding that has no application here, where the retiree class is separately represented and the UAW does not purport to represent it in any judicial or extra-judicial proceeding.

56. As noted in the Findings of Fact, UAW has a long history of bargaining with Ford over retiree issues, including notably improvements in retiree health-care benefits, and of using its members' dues to defend retirees' benefits in court where necessary. In this case, UAW entered into negotiations with Ford with the aim of reaching a settlement that would, in a way that was fair to retirees, provide Ford with a level of cost savings that would increase the likelihood that it would survive and continue to pay promised benefits in the future; indeed, the settlement framework UAW negotiated was more advantageous to the retirees than any agreement negotiated solely on their behalf without UAW's involvement could have been.

57. Bronson contends that "UAW negotiated a deal that is far more beneficial to current Ford employees than to retirees." (Docket No. 739, Objection at 14) Bronson emphasizes, in particular, that most of the changes in retiree health-care benefits introduced under the Settlement are not applied to the health-care benefits of active employees. (*See id.* at 14) But his conclusion that the Settlement is therefore skewed in favor of active employees overlooks

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two important points.

***30** 58. First, if the Settlement is approved, the changes in retiree health benefits will apply to all currently active employees upon retirement, just as they will to currently retired employees. (Docket No. 24, Ex. 1, Proposed Settlement Agreement § 2.) The active employees, in other words, have accepted the same changes in their retiree health care. This is particularly significant in view of the fact that one quarter of Ford's UAW-represented workforce is eligible for retirement. (See Docket No. 896, Bantom Decl. at 18)

59. Second, while most changes in retiree health-care are not applicable to the benefits of active employees, these employees are contributing to the Settlement in another way that is much more costly for them and much more beneficial to the retirees-by giving up an average of \$2,000 per year in wages initially to help fund the DC-VEBA that will mitigate health care costs for retirees. (See Docket No. 24, Ex. 1, Proposed Settlement Agreement § 13.B) Thus, as Judge Cleland noted with respect to the GM settlement, "active employees will 'participate' in the give-back twice." *UAW v. GM*, 2006 WL 891151, at *7. Bronson's assertion that the settlement framework UAW negotiated was "far more beneficial to current Ford employees than to retirees," (Docket No. 739, Objection at 14), is unfounded.

60. These reductions in active workers' compensation packages could not have been negotiated without the UAW's participation on behalf of the retirees. The UAW is the sole bargaining representative for its members, and therefore the only body authorized to agree to divert active employees' scheduled wage increases to the DC-VEBA.

61. In a related argument, counsel for Bronson argued at the Fairness Hearing that, under the CBA, active employees who were hired after 1996 are not entitled to health care upon retirement, and that they therefore have no stake in the modification of retiree health benefits. This argument is based on an erroneous reading of the eligibility provision of the CBA, which provides that employees hired after September

30, 1996 who have less than ten years of service will not be eligible for health care benefits in retirement. (See Docket No. 884, Ex. J, Moog Decl. Ex. 2, H-S-M-D-D-V § 4(d)(3)) There is no evidence to support an inference that the active employees who ratified the MOU will be unaffected at retirement because they will have an insufficient period of service to be eligible for retiree health benefits.

62. Bronson also argues that, on the alleged advice of its financial experts, UAW decided to negotiate concessions on retiree health care during 2005 for the purpose of improving its negotiating position on behalf of active employees when its collective bargaining agreement expires in 2007. (*Id.* at 14) The evidence does not support this assertion. UAW asked Lazard to analyze Ford's financial condition and, if concessions appeared necessary, to "evaluate the extent to which relief from Ford's retiree health obligations would improve Ford's prospects." (Docket No. 896, Bantom Decl. ¶ 16) "Lazard was never instructed to devise or analyze healthcare relief proposals with a goal to benefit active employees at the expense of retirees...." (Docket No. 890, Yearley Decl. ¶ 9) UAW agreed to negotiate with Ford in late 2005 because UAW concluded, based on advice received from its financial consultants, that this was the best time to secure the best deal for retirees. (See Docket No. 896, Bantom Decl. ¶¶ 18-20) There is nothing in any of the Lazard reports that suggests otherwise, nor is there anything in the record that supports Bronson's assertion.

***31** 63. Last, the fact remains that, regardless of UAW's wishes, there could and would have been no settlement of this litigation without the independent decision of Class Counsel to enter into the Settlement. And, as the Court has previously observed, Class Counsel are highly qualified to represent the class in this litigation, regardless of whether it was litigated or settled. (See Order (Docket No. 36) (Feb 24, 2006) (appointing Class Counsel))

(b). *Objection Relating To The Adequacy Of The Class*

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Representatives And Class Counsel

64. Bronson also complains that the Settlement is unfair because it was not the product of “arm’s length negotiations involving Class Counsel.” (Docket No. 739, Objection at 30) This argument is founded on the claim addressed above, that in undertaking its negotiations with Ford prior to the initiation of the lawsuit, UAW favored its active employees over the retirees, and that the class representatives and Class Counsel merely and uncritically supported the pre-suit negotiation position of the UAW. Bronson has offered no evidence to support his contention.

65. The evidence established that the class representatives and Class Counsel have an undivided loyalty to the class. The fact that the UAW is also participating as a plaintiff (represented by separate counsel) does not disturb the cohesiveness of the class or the loyalty of Class Counsel and the class representatives. This separate representation of the class provides the “structural protection” that  Rule 23 requires.  *Ortiz v. Fibreboard Corp.*, 527 U.S. 815, 855, 119 S.Ct. 2295, 144 L.Ed.2d 715 (1999).

66. Although the framework of the Agreement was developed by UAW in negotiations with Ford, Class Counsel and the class representatives could have rejected the settlement at any time, based on their own independent evaluation. Class Counsel represent a cohesive class, they are expert in retiree benefits litigation, and they are entirely capable of determining whether the final Agreement they participated in negotiating-and that they could have rejected at any point-sufficiently protected the interests of the class. See *In re Diet Drugs Prods. Liab. Litig.*, 2000 U.S. Dist. LEXIS 12275, at *135-36 (E.D.Pa. Aug. 28, 2000) (unpublished) (counsel was “qualified to make assessments of the extent to which he or she needed to be involved in the negotiations”). Nothing in  Rule 23 or the cases cited by the Bronson Objectors “requires that ... counsel fight among one another or attend every negotiation session.” *Id.* at *159. See also *UAW v. GM*, 2006 WL 891151, at *26 (“In short, regardless of UAW’s

wishes, there could and would have been no settlement of this litigation without the independent decision of counsel appointed by this Court to represent the class to enter into the settlement.”).

67. At bottom, Bronson’s complaint is that he or his counsel would have negotiated a different agreement or no agreement at all. But even if true, that is not a sound basis for an objection. The fact that some class members would prefer to litigate claims rather than compromise them, or would “press for more drastic relief,” raises no issue of inadequate representation.

 *United States v. City of New York*, 198 F.3d 360, 367 (2d Cir.1999) (“Representation is not inadequate simply because ‘the applicant would insist on more elaborate ... pre-settlement procedures or press for more drastic relief’ or has ‘different views on the facts, the applicable law, or the likelihood of success of a particular litigation strategy’ ”);  *In re NASDAQ Market-Makers Antitrust Litig.*, 187 F.R.D. 465, 491 (S.D.N.Y.1998) (where an allegation of inadequate representation rests on fact that class counsel negotiated a settlement of which he did not approve, this issue can be addressed through the court’s consideration of objections). Nor is class representation inadequate merely because the objectors disagree with particular terms of the settlement. See, e.g.,  *DeBoer v. Mellon Mortg. Co.*, 64 F.3d 1171, 1175, 1177 (8th Cir.1995) (disagreement with settlement terms does not demonstrate that class representation was inadequate);  *Bradley v. Milliken*, 828 F.2d 1186, 1192 (6th Cir.1987) (“A mere disagreement over litigation strategy or individual aspects of a remediation plan does not, in and of itself, establish inadequacy of representation.”). To hold that an objector’s disagreement with the settlement terms made class representation inadequate “would require decertification any time an objection is raised to a class, certainly not the standard envisioned by  Rule 23.”  *DeBoer*, 64 F.3d at 1175.

b. Bronson’s objection concerning due process and the Seventh Amendment

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¶ 68. Bronson contends that certification of a Rule 23(b)(2) class violates due process and the Seventh Amendment because “this [S]ettlement takes away money to which Ford retirees otherwise would have a claim.” (Docket No. 739, Objection at 28-29) Bronson argues that the class certification should include opt-out rights because “if Ford reduced health benefit payments to individual retirees, the affected retirees would have a money claim to recover those benefits amounts back from Ford.” *Id.* at 27.

69. First, Bronson contends that class treatment is “problematic” in this case, citing references in [Ortiz v. Fibreboard](#), 527 U.S. 815, 119 S.Ct. 2295, 144 L.Ed.2d 715 (1990) to the Seventh Amendment right to a jury trial and due process. Bronson then goes on to argue that, for this reason, mandatory [Rule 23\(b\)\(2\)](#) certification is inappropriate. *Fibreboard*, however, applies only to limited fund class actions brought under [FED. R. CIV. P. 23\(b\)\(1\)\(B\)](#), not to cases primarily for injunctive relief, like the case here, brought pursuant to [Rule 23\(b\)\(2\)](#).

70. *Fibreboard* involved complicated individual damage claims for asbestos exposure, as well as Seventh Amendment jury trial rights of absent class members-both of which are reasons for allowing opt-out under [Rule 23\(b\)\(3\)](#). That case, which involved a proposed global settlement of future claims against a manufacturer of asbestos-containing products, concerned “the difficulties facing limited fund treatment of huge numbers of actions for unliquidated damages arising from mass torts, the first such hurdle being a computation of the total claims.” *Id.* at 850. However, *Fibreboard* is not implicated absent a fund that is limited independently of agreement by the parties.

71. By contrast, this case is an “action for a declaratory judgment” seeking declaratory and injunctive relief under ERISA Section 502(a)(1)(B), (a)(3) and [Section 301](#) of the Labor Management Relations Act (“LMRA”). (Am. Com. pl. ¶¶ 2-4, 34 (“seek[ing] a declaration that rights to retiree health care benefits cannot be unilaterally terminated or

modified by Ford, and a permanent injunction prohibiting such termination or modification”)) This action was filed before Ford made any modifications to retiree health benefits, and consequently does not raise any issues that could result in money damages, much less a limited fund. *See, e.g.*, [Berger v. Xerox Corp. Ret. Income Guar. Plan](#), 338 F.3d 755, 763-64 (7th Cir.2003) (affirming [Rule 23\(b\)\(2\)](#) certification of declaratory judgment claim by pension plan participants “to recover benefits” under ERISA § 502(a)(1)(B)).

72. Instead, the class has a common claim (that their benefits are vested) that “is susceptible to a single proof and subject to a single injunctive remedy,” and no possible claim for money damages. [Senter v. General Motors Corp.](#), 532 F.2d 511, 525 (6th Cir.1976).

73. Similarly, because the plaintiffs in this case were seeking purely prospective, equitable relief, they would not be entitled to a jury trial. *See* [Great-West Life & Annuity Ins. Co. v. Knudson](#), 534 U.S. 204, 221, 122 S.Ct. 708, 151 L.Ed.2d 635 (2002) (ERISA “§ 502(a)(3), by its terms, only allows for equitable relief”).

*33 74. Because the claims implicated in the Settlement Agreement seek only injunctive and declaratory relief, they are indisputably appropriate for mandatory class treatment pursuant to [Rule 23\(b\)\(2\)](#). *See* [FED. R. CIV. P. 23\(b\)\(2\)](#) Advisory Committee’s Note; [Amchem Products Inc. v. Windsor](#), 521 U.S. 591, 614, 117 S.Ct. 2231, 138 L.Ed.2d 689 (1997).

75. Although Bronson alleges in his complaint that the claims are “properly maintained as a class action under” [Rule 23\(b\)\(2\)](#), (*see Bronson v. Ford*, Civ. No. 06-10331, E.D. Mich., Docket No. 1, ¶ 14), he nonetheless argues that class members should be allowed to opt-out. But in each of the cases relied upon by Bronson, the class sought both injunctive relief and monetary damages or involved individually varying claims where “individual class members may be able to make even stronger claims based on their own individual

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circumstances.” *Fuller v. Fruehauf Trailer Corp.*, 168 F.R.D. 588, 593, 603 n. 26, 605 (E.D.Mich.1996) (alleging, in addition to an ERISA claim, a RICO claim for money damages).

76. Allowing class members to opt out from a unified class would necessarily mean that different retirees could have different rights under the same Ford health care plan, which would make effective declaratory or injunctive relief impossible, and would make the administration of benefits under the Settlement unworkable. See *Day v. NLO*, 851 F.Supp. 869, 885 (S.D.Ohio 1994) (“Opting out is generally not reasonable because plaintiff-by-plaintiff injunctive relief is not practical.”). It would also “defeat the fundamental objective of (b)(2), to bind the members of the class with one conclusive adjudication.” *Kyriazi v. W. Elec. Co.*, 647 F.2d 388, 393 (3d Cir.1981) (citation omitted); *Ass’n for Disabled Ams., Inc. v. Amoco Oil Co.*, 211 F.R.D. at 473 (same); *Stewart v. Rubin*, 948 F.Supp. 1077, 1090 (D.D.C.1996) (Rule 23(b)(2) is “designed specifically to avoid the risks of inconsistency, prejudice, or inequity that would result to persons similarly situated in the absence of a unitary adjudication of their common claims.”); *Heit v. Van Ochten*, 126 F.Supp.2d at 493. See also *UAW v. GM*, 2006 WL 891151, at *31-*32 (confirming certification of Rule 23(b)(2) class without opt-out right). Furthermore, contrary to Bronson’s suggestion, in an equitable class action such as this one, neither minimum contacts nor consent to the forum’s jurisdiction is necessary to satisfy due process. E.g., *In re Joint E. & S. Dist. Asbestos Litig.*, 78 F.3d 764, 777-78 (2d Cir.1996); *Avagliano v. Sumitomo Shoji Am., Inc.*, 107 F.R.D. 748, 749-50 (S.D.N.Y.1985).

c. Bronson’s Objections To Particular Settlement Terms

77. The Hold Harmless Provision. Bronson objects

to the modification of the health plan’s hold harmless provision under the Settlement Agreement. Under the current program, if a retiree receives services from a provider participating in one of the available health plans, that provider is obligated by agreement with the plan’s administrator to charge only the rate agreed with the relevant Plan and cannot bill the retiree for any unpaid balance. If a retiree elects to obtain care from a non-participating provider, one who has not agreed to abstain from “balance billing” the retiree, the Plan reimburses the provider up to the “reasonable and customary” amount charged by participating physicians. (Docket No. 884, Ex. K, Mezza Decl. ¶ 7 & Ex. 2) The administrator will then defend that amount against a non-participating provider’s claims for additional payment from a retiree (unless the retiree has entered an agreement with the provider regarding the charges). (*Id.*)

*34 78. Under the Settlement Agreement, the hold harmless provision is modified by removing the administrator’s obligation to defend the “reasonable and customary” charges in the event a non-participating provider balance bills a retiree and then pursues him or her for payment. (See *id.* ¶ 10 & Ex. 1; Docket No. 24, Ex. 1, Proposed Settlement Agreement, Ex. 1, at 4-5) Thus, if a retiree obtains services from a participating provider, the change has no effect on payment to that provider. If a retiree elects to obtain medical services from a non-participating physician, he or she will be responsible for any charges beyond the “reasonable and customary” amount that participant physicians had agreed to accept for those services. (Docket No. 24, Ex. 1, Proposed Settlement Agreement, Ex. 1, at 4-5; Docket No. 884, Ex. K, Mezza Decl. ¶ 10)

79. Under the Settlement Agreement, the effect of the modification is relatively minor. First, it applies *only* when the retiree elects to obtain service from a non-participating provider. Under the Agreement, the retiree will *not* be responsible for any additional charges if he “d[id] not have the ability or control to select a [participating] provider to perform the service.” (Docket No. 24, Ex. 1, Proposed Settlement Agreement, Ex. 1, at 5; see also Docket No. 884, Ex. K, Mezza Decl. ¶ 12) For example, if the retiree undergoes surgery at a participant hospital with a participant physician, but a

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member of the surgical team, such as the anesthesiologist, is a non-participant, the retiree would not be responsible for any additional charges by that non-participating member of the team. (Docket No. 884, Ex. K, Mezza Decl. ¶ 12.) Retirees may also avoid extra charges for an out-of-network provider by first obtaining a referral. (*Id.*) Also, retirees without appropriate geographic access to an in-network primary care provider, obstetrician/gynecologist, or pediatrician may, without additional out-of-pocket expense, receive care from an out-of-network provider by obtaining an out-of-area waiver. (*Id.* ¶ 13)

80. The Katz Declaration on which Bronson relies ignores these safeguards-Katz claims, for example, that “patients may have less access to a highly experienced orthopedic surgeon because the anesthesia group the surgeon works with is not in the plan network”-and rests on speculation. (Docket No. 739, Katz Decl. ¶ 6.) Dr. Katz did not base his opinions on the relevant facts of this case, such as the coverage terms of the Ford health plan, the size, breadth, and depth of the provider networks (including participating specialists and their reasonable and customary rates), which number over 650,000, and the Ford retiree population. Thus, there is no support for his supposition concerning the “potential” effect of the Settlement on the plaintiffs if certain speculative conditions occur. Consequently, his opinion is unreliable and unhelpful to the Court’s analysis. See, e.g., *Brainard v. Am. Skandia Life Assur. Corp.*, 432 F.3d 655, 664 (6th Cir.2005) (within court’s discretion to discard affidavit in the absence of meaningful analysis because “an expert opinion must ‘set forth facts’ and, in doing so, outline a line of reasoning arising from a logical foundation”) (citation omitted).

*35 81. As modified by the Settlement Agreement, the hold harmless provision is intended to conform Ford’s plan to the common practice of health plans, and to reasonably control costs by providing an incentive for retirees to select from a wide network of participating providers for their health care services. Considering the common use of this feature in health plans and the protections built

into the Settlement, the modification of the hold harmless provision does not provide a basis for disapproving the Settlement. See *UAW v. GM*, 2006 WL 891151, at *29-*31 (rejecting precisely the same argument);

82. DC-VEBA Funding. Bronson questions the sufficiency of the funding for the DC-VEBA, and posits that Ford’s share of the funding is necessarily suspect because, scaled by the number of retirees, GM provided a proportionately larger contribution to fund a DC-VEBA under its similar settlement agreement. (See, e.g., Docket No. 739, Objection at 22)

83. The DC-VEBA is to be funded in large part by wage and cost-of-living deferrals by active employees averaging \$2,000 in the first year and increasing in subsequent years, as well as by \$108 million in cash contributions by Ford. (Docket No. 896, Bantom Decl. at ¶ 34 & Ex. A at 4; see Docket No. 24, Ex. 1, Proposed Settlement Agreement § 13) Based on these sources, UAW’s actuarial consultants have determined that “the DC VEBA is projected to have sufficient assets over a twenty year period to provide for the level of mitigation payments anticipated in the current Settlement Agreement [.]” (Docket No. 896, Taranto Decl., Ex. A at 3) In fact, even without any additional contributions arising from special dividends or proceeds from stock appreciation rights, Milliman estimates that the DC-VEBA will carry a \$2 billion *surplus* at the end of twenty years. Even if the DC-VEBA’s investment return should average only 3% over the 20 year period-which even Bronson’s expert seems to suggest is a low estimate (Docket No. 739, Ex. 5, Wobbeling Decl. ¶ 18)-the DC-VEBA would be left with a balance of \$1.4 billion after 20 years. (Docket No. 896, Taranto Decl., Ex. A at 3) In addition, proceeds for stock dividends or stock appreciation rights may provide additional funding to the DC-VEBA for mitigation purposes. But the forecast that the DC-VEBA will be viable for the 20-year period is in no way dependent on such additional contributions.

84. Bronson’s comparison of the ratio of class size to DC-VEBA contribution misunderstands the factors that effect Ford’s contribution as

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compared to GM's. The evidence established that because Ford has slightly more than two retirees for each active worker, compared to GM's five retirees for each active worker, the contributions by Ford active workers to the DC-VEBA more than compensate for the lower contribution by Ford. (Docket No. 896, Taranto Decl. at ¶ 19)

85. Bronson also complains that Ford does not provide a "guaranty" of the adequacy of the DC-VEBA, citing Settlement Agreement ¶ 14.A (Docket No. 739, Objection at 36), but that provision primarily reflects the fact that under the Agreement, Ford will have no role in the operation of the mitigation plan or the maintenance and administration of the DC-VEBA, which will be entirely independent and separate from the company. To the extent that the DC-VEBA funding and return on DC-VEBA investment exceeds expectations, retirees' benefits will be further enhanced beyond the expected mitigation amounts, and such mitigation decisions will be made by the committee that operates the DC-VEBA, a committee that is entirely independent of Ford. (See Docket No. 24, Ex. 1, Proposed Settlement Agreement § 14.B) More fundamentally, retiree health care benefits under the current agreements are not guaranteed in the sense of being fully funded, any more than they are by virtually any other employer. One of the primary reasons for the Settlement is to help place Ford on a financial footing that will provide greater assurance that it will be able to provide benefits into future years, and as plaintiffs' expert has concluded, if the Settlement is approved, the mitigation amounts *will* be "guaranteed," in the sense of being adequately funded, by the assets of the DC-VEBA.

*36 86. Settlement Termination. Bronson also objects that Ford or UAW may terminate the Settlement Agreement in 2011, but that class members may not. While Ford or the UAW can terminate the Settlement beginning in September 2011, the effect of any such termination by Ford would be to return the retirees to their pre-Settlement position. If Ford terminates the agreement and were again to assert its present position that it is entitled

unilaterally to modify or terminate the retiree's benefits, the Settlement Agreement provides that the dispute over that issue would be decided on the basis of the case law as it exists on the date the Settlement is approved. (*Id.* at § 19(B)(b)) After 2011, therefore, class members may continue with the modified health benefits provided under the Settlement Agreement, or, if Ford terminates the agreement, they will return to the position they were in before the Settlement.

87. Medicare Coordination And The ADEA. Bronson takes issue with the Medicare coordination provision of the Settlement, claiming it is unfair to class members over age 65, and that it violates the Age Discrimination in Employment Act ("ADEA"). (Docket No. 739, Objection at 26, 32-34) This argument is founded on a misapprehension about the current Ford health plan. Medicare coordination is already in place under the current program for retirees who are enrolled in Medicare (*see* Moog Decl. Ex. 2, H-S-M-D-D-V Prog. § 11), and in fact five of the class representatives are currently enrolled in Medicare. (See Supplemental Declaration of Dennis DePaulis ¶ 5, attached hereto as Exhibit 1) For Medicare-enrolled retirees, Medicare is the primary payer and the Ford health plan is the secondary payer, with the effect that the Medicare-enrolled retiree ultimately receives the same total benefit, notwithstanding that some portion of the cost is paid by Medicare. (See Docket No. 884, Ex. K, Mezza Decl. ¶ 14) The Settlement Agreement does not change the existing policy, so the fact that the Modified Plan continues to require Medicare coordination provides no basis for disapproval of the Settlement.

88. Bronson argues that Medicare coordination is "illegal" under the ADEA because a plan may not "reduce health benefits for retirees age 65 or older by coordinating with Medicare, unless the plan specifically includes a corresponding cost reduction for younger plan participants or some other corresponding increase in benefits to those over 65," *citing*  *Erie County Retirees Ass'n v. County of Erie, Pa.*, 220 F.3d 193 (3d Cir.2000). (Docket No. 739, Objection at 32) Erie County involved a group of retirees aged

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65 and older (*i.e.*, Medicare-eligible) who sued their former employer because they were provided a health care plan that was different and inferior to the plan available to retirees who had not reached the age of Medicare eligibility.

220 F.3d at 196. Younger retirees were provided a traditional indemnity plan, while those 65 or older were only provided with an HMO. *Id.* at 197. The retirees appealed from a summary judgment ruling that “the ADEA clearly was not intended to apply to retirees, like the Plaintiffs here, who premise their complaint on alleged disparities in their retirement health benefits based on Medicare-eligibility.” 220 F.3d at 200. The Third Circuit reversed and held that, to comply with the ADEA, the County’s retiree health plans must provide either “equal benefit[s]” to all retirees or incur “equal cost” for benefits for all retirees. *Id.* at 216.

*37 89. In contrast to *Erie County*, Ford retirees under 65, and retirees 65 and over, participate in the same plan and receive the same benefits, currently and under the Settlement. In addition, Ford provides retired hourly employees enrolled in Medicare with a Medicare supplement of the cost of the premium paid by Medicare enrollees. (Supp. DePaulis Decl. ¶ 6) Very few employers provide a comparable payment.

90. Moreover, although Bronson suggests that coordination with Medicare is illegal under *Erie County*, the Third Circuit only remanded the case, instructing that, in applying the “equal benefit” prong of the analysis, Medicare benefits “should” be taken into account along with the employer-provided benefits. 220 F.3d at 216 (emphasis added). On remand, the district court considered whether the employer-provided benefits and the Medicare-provided benefits together met the “equal benefits” requirement. *Erie County Retirees Ass’n v. County of Erie*, 140 F.Supp.2d 466, 470 (W.D.Pa.2001). In doing so, the district court relied upon the governing EEOC regulation, which provided that, “it is not necessary for an employer to provide health benefits which are otherwise provided to certain employees by Medicare.” *Id.* at 470 (citing

29 C.F.R. § 1625.10(e)). Under the regulation, coordination with Medicare is impermissible only if, “taking the employer-provided and Government-provided benefits together, an older employee is entitled to a lesser benefit of any type ... than a similarly situated younger employee [.]” *Id.* While the court found for plaintiffs, because the HMO provided for the Medicare-eligible plaintiffs was inferior to the indemnity plan available to younger retirees, nothing in *Erie County* prohibits Medicare coordination where, as here, benefits available to older retirees are not inferior to those available to those under 65.

91. Ford’s coordination of benefits with Medicare is compliant with EEOC regulations. The relevant law is clear that coordinating benefits with Medicare, as done under the existing program and as would be continued under the Settlement, is permissible. It is also a commonplace feature of employer-provided health plans. (See Docket No. 884, Ex. K, Mezza Decl. ¶ 14; Ex. E, Borzi Decl. ¶ 14) In any event, the objection has no merit because the Settlement does not alter existing policy under the current plan.

92. Necessity of Subclasses. Bronson also argues that the class should have been broken into subclasses so that class members with pensions of \$8,000 per year or less, who retain their existing health coverage, and class members over age 65, who receive part of their benefits through Medicare, have their own counsel. (Docket No. 739, Objection at 25-27) But “‘there is no rule that settlements benefit all class members equally, ... as long as the settlement terms are ‘rationally based on legitimate considerations.’” *UAW v. GM*, 2006 WL 891151, at *28 (citing cases); see also *id.* at *11 (to “require the class to be fragmented based on minute individual differences divorced from any notion of antagonism ... would endanger the class action device and discourage settlements.”). Since all class members have the same fundamental interest in maintaining health care, it is no impediment to class treatment that the Settlement provides extra protection for the most vulnerable class members. *Id.* Nor are subclasses required to separate retirees under age 65 and age 65 and older. Retirees over age

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65 receive the same benefits as retirees under age 65, except that older retirees receive part of their health insurance from the federal government instead of from Ford. For that reason, their interests are not materially different from or antagonistic to those of class members under age 65. In any event, the class representatives include both Protected Retirees and General Retirees as well as five retirees who are over age 65 and enrolled in Medicare. (See Ex. 1, Supp. DePaulis Decl. ¶¶ 4-5) The participation of class representatives with these various characteristics supports the conclusion that subclasses are not warranted.

d. Bronson's objection concerning the applicability of the Federal Rules of Evidence

*38 93. Bronson argues in a lengthy footnote that the Lazard and Milliman reports submitted by the UAW-and expert reports submitted by the other parties-are inadmissible because they do not comply with the requirements of [Federal Rule of Evidence 702](#).

94. Many appellate courts have implicitly approved the use of affidavits or declarations in evaluating the fairness of class action settlements. E.g., [Newby v. Enron Corp.](#), 394 F.3d 296, 307 (5th Cir.2004); [In re Rite Aid Corp. Sec. Litig.](#), 396 F.3d 294, 298 (3d Cir.2005) (expert declaration submitted in connection with fee request); [Petrovic v. Amoco Oil Co.](#), 200 F.3d 1140, 1149 (8th Cir.1999). The Court is aware of only a single, unreported case in which a district court in such a proceeding has declined to consider affidavits (which ultimately proved cumulative) on hearsay grounds. [Dumont v. Charles Schwab & Co., Inc.](#), No. CIV.A 99-2840, 2000 WL 1023231 (E.D.La. July 21, 2000) (nonetheless approving settlement).

95. While the Court need not reach this issue, because it is entitled to consider anything it deems helpful in evaluating the Settlement, it is clear that the expert opinions presented by Lazard and Milliman would be admissible

because they are relevant and reliable, and they easily meet the requirements set forth by [Federal Rule of Evidence 702](#) and the Supreme Court's decision in [Daubert v. Merrell Dow Pharmaceuticals, Inc.](#), 509 U.S. 579, 597, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). Lazard and Milliman are leading investment banking and health care actuarial firms, respectively, in the nation. The qualifications and experience of Andrew Yearley, Suzanne Taranto, and Drew Davidoff, explained in the declarations accompanying their reports, attest to their ability to conduct financial and actuarial analysis. See, e.g., [United States v. Majors](#), 196 F.3d 1206, 1215 (11th Cir.1999) (proper for district court to admit opinion rendered by accountant because the expert had eight and one-half years' experience as a financial analyst). The Lazard and Milliman reports themselves carefully explain the tasks performed, steps taken, and assumptions used, so that the Court can properly assign weight to the opinions expressed. The reports are not required to re-create for the Court each calculation performed over the course of these experts' extensive involvement with Ford; that would defeat the purpose of an expert report, which is to distill the expert's conclusions in a manner understandable and helpful to the Court. For these reasons, the Court concludes that it is appropriate to consider the expert reports and declarations submitted by the parties. The Court also notes that Bronson could have provided detailed expert analyses of the data on the same subject matter, as the underlying data were available to him, but he chose not to do so.

e. Bronson's objections relating to class notice

96. Notice of a class settlement need only "fairly apprise the prospective members of the class of the terms of the proposed settlement and of the options that are open to them in connection with [the] proceedings." [Weinberger v. Kendrick](#), 698 F.2d 61, 70 (2d Cir.1982) (quotation and citation omitted). Class Notice "can practicably contain only a limited amount of information," and, therefore, may properly be limited to "very general descriptions of

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the proposed settlement.” *Id.* (See also Docket No. 739, Objection at 38) The Class Notice that the Court approved satisfies Rule 23(e). It explained the background of the litigation, summarized the terms of the Settlement, and advised class members of their right to object. It also included a complete copy of the Settlement Agreement and an explanatory letter written by Class Counsel and the UAW.

*39 97. Bronson objects to the Class Notice primarily on the ground that it does not include his views on the wisdom of the Settlement or the circumstances that led to it, and that it does not highlight terms that Bronson deems to be important. But a summary necessarily does not include every term. “The mere fact that the notices do not fully explore [certain issues] is immaterial. Class members are not expected to rely upon the notices as a complete source of settlement information.... Any ambiguities regarding the substantive aspects of the settlement could be cleared up by obtaining a copy of the agreement.” Grunin v. Int'l House of Pancakes, 513 F.2d 114, 122 (8th Cir.1975). In this case, a copy of the Settlement Agreement was mailed to each class member along with the notice and for that reason Bronson’s objection on this point is not well founded.

98. Other objections raised by Bronson concerning the Class Notice are wrong as a factual matter. For example, Bronson complains that the Notice “failed to mention anywhere ... the elimination of ‘hold harmless protection’ , relating fees above the reasonable and customary charge for health care services provided by a non-participating physician. But the Notice expressly states that “Administrative Changes” under the Settlement include “*limitations on Ford's responsibility for all fees charged above those reasonable and customary,*” and that “[m]ore information concerning Administrative Changes is set forth in Exhibit 1 to the Settlement Agreement.” (Docket No. 883, Passarella Decl. Ex. 1, Class Notice at 3)

99. Last, Bronson accuses Ford and UAW of trying to “confuse and intimidate retirees” from objecting by mailing the retirees a postcard

encouraging them to authorize pension deductions to pay for monthly premiums under the Modified Plan in the event that the Settlement is approved. The evidence does not support Bronson’s view. In mid-April, Ford and UAW mailed to class members a form authorizing monthly deductions from pension benefits of the health-care premiums that will be required if the Settlement Agreement is approved by the Court. The form informed recipients that “[t]he Court has not yet approved the health care Settlement Agreement[,]” (Docket No. 739, Bronson Objection, Ex. 17), and clearly stated, at two different points, that “[i]f the Court does not approve the health care Settlement Agreement, the authorization will not be used to make any deductions.” (*Id.*) The form also explained that it was mailed to class members before the Court ruled on settlement approval because, in the event the Settlement was approved, class members who had not authorized pension deductions would be enrolled in the “catastrophic plan,” which covers only major health care expenses. The deduction form was mailed to class members prior to approval of the Settlement to minimize the danger that retirees might be placed in the catastrophic plan simply because of a failure to complete the necessary paperwork in a timely fashion. The Court concludes that the mailing does not warrant disapproval of the Settlement.

ii. Objections raised by Dennis Lapso.

*40 100. Objector Dennis Lapso has asked the Court to “defer ruling on the fairness of the proposed [S]ettlement until completion of appeals he has filed to the UAW’s Convention Appeals Committee” (“CAC”) and further asked the Court to issue an order requiring the CAC to hear his appeal at the UAW annual convention and to issue a ruling expeditiously. (Docket No. 898, Memorandum of Dennis Lapso Objecting to Proposed Settlement at 19)

101. There is no basis for the Court to delay its decision with respect to settlement approval pending Lapso’s internal union appeal. Based on the decision of the CAC denying a similar

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internal appeal relating to the GM settlement, Objector Lapso withdrew his arguments relating to his claim that retirees should have had the right to vote on the settlement and his claim based on facts alleged in one unsigned affidavit. (Docket No. 905, Tr. at 51-52) His appeal is therefore now based only on the timing of the ratification vote in one local union, Local 1250. However, the provision of the UAW Constitution cited by Objector Lapso requires only that ratification votes take place “at a meeting ... or through such procedure ... to encourage greater participation of members in voting.” UAW Article 19 § 3 (emphasis added). Lapso does not allege that the vote did not take place at a meeting, but only that he would have preferred the meeting to take place on a different date. (Docket No. 898, Lapso Objection at 10-11) His assertion that the ratification procedure violated the UAW Constitution thus does not appear to have merit and does not provide a reason for the Court to defer its ruling on the fairness of the Settlement. That is especially so in view of the importance to Ford of implementation of the Settlement as soon as possible. Indeed, the importance of the implementation of this settlement as soon as possible is important to the class as well, insofar as it provides significant benefits to the viability of Ford, the provider of their medical benefits, and also benefits the class by the monetary contributions of active Ford UAW member employees.

E. Motion For Fees And Expenses.

101. On March 23, 2006, Class Counsel submitted a motion for fees and expenses (Docket No. 131) The Court rules that Class Counsel’s requested hourly rates are reasonable and appropriate pursuant to Settlement Agreement Section 20.B and given the size of the settlement and the extensive legal work performed. The Court approves a request for reasonable fees and expenses by Class Counsel, and will determine the exact amount of such fees and expenses after a motion made within 14 days pursuant to Rule 54(d)(2). Similarly, the UAW is to file its motion for reasonable attorney and professional fees, also pursuant to Section 20.B of

the Settlement Agreement, within 14 days after judgment pursuant to Rule 54(d)(2), and the Court will rule on UAW’s fee motion at that time. The amounts of fees and expenses awarded to both Class Counsel and to UAW will be set forth in a supplemental order that will be incorporated into the Court’s judgment.

F. Settlement Is Without Prejudice

*41 102. The parties have agreed that in the event the Settlement Agreement is terminated pursuant to its Sections 17 or 18, all parties will remain protected by the “No Admissions; No Prejudice” provisions set forth in Section 19 of the Agreement. The Court expressly confirms the provisions of Section 19 of the Settlement Agreement, and incorporates them herein as if fully set forth.

G. Indemnification

103. In the Settlement Agreement, the parties have agreed that Ford will indemnify UAW, and its officers, directors, and employees, and reimburse their reasonable attorneys’ fees and expenses on the basis set forth in Section 20.A of the Settlement Agreement. (Docket No. # 24, Ex. 1, Settlement Agreement § 20.A) The Court finds such a provision is reasonable.

H. Releases

104. In consideration of Ford’s entry into the Settlement Agreement and the other obligations of Ford contained therein, the class representatives, the Class Counsel, and the UAW consent to the entry of this Judgment, which will be binding upon all class members pursuant to [Rule 23\(b\) of the Federal Rules of Civil Procedure](#). All of the release provisions set forth in the Settlement Agreement shall be binding upon the parties and class members as set forth in that Agreement.

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I. Retention of Jurisdiction

105. Pursuant to Section 22.B of the Settlement Agreement, the Court retains exclusive jurisdiction to resolve any disputes relating to or arising out of or in connection with the enforcement, interpretation or implementation of the Settlement Agreement. See  *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 382, 114 S.Ct. 1673, 128 L.Ed.2d 391 (1994) (a district court retains jurisdiction to enforce a settlement agreement if it either (1) has language in the dismissal order indicating its retention of jurisdiction, or (2) incorporates the terms of the settlement agreement into the dismissal order); *RE/  MAX Int'l, Inc. v. Realty One, Inc.*, 271 F.3d 633, 645 (6th Cir. 2001) (same).

106. For the foregoing reasons, the Court concludes that the Settlement is fair, reasonable and adequate, and  PROVES the parties' Settlement Agreement in all respects and as to all parties, including Ford, UAW, class representatives, and class members. The plaintiffs' claims, including the claims of the class, are hereby DISMISSED with prejudice pursuant to  *Federal Rules of Civil Procedure 41(a)(2)* and  *23(e)(1)(A)* and *(C)*, subject to the Court's retention of jurisdiction as stated above.
PH0H=SO ORDERED.CC=CERTIFICATE OF SERVICE

GOODINE, J.

Copies of this Order were served on the attorneys of record by electronic means or U.S. Mail on July 13, 2006.

All Citations

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III. CONCLUSION

Footnotes

¹ This Court notes that a significant portion of the parties' jointly-proposed findings of fact are not contradicted. The Bronson Objectors, though, have stated objections to a number of the proposed findings of facts and conclusions of law.

The Court rejects the Objector's contentions and, in large part, adopts the parties' "Joint Proposed Findings of Fact and Conclusions of Law." Some portions of the joint proposed findings and conclusions are not included in this order because the Court believes that those points are covered elsewhere in the order, not because the Court disagrees with those unadopted propositions. The Court finds that all important jointly proposed findings are supported by record evidence, and those proposed findings which are not included in this Order have been omitted for conciseness.

² Judge Tarnow subsequently recused himself from the case. Judge Anna Diggs Taylor was reassigned to the case, and thereafter recused herself. The case was then reassigned to the undersigned.

³ On March 31, 2006, U.S. District Judge Robert Cleland entered an order approving a class action settlement in *UAW et. al v. General Motors*, Case No. 05-CV-73991-DT, 2006 WL 891151 (E.D.Mich. March 31, 2006) (unpublished), a case similar to the instant case.

Exhibit 9

Microsoft I-V Cases, No. J.C.C.P. No. 4106,
2002-2 Trade Cas. ¶ 73,013 (Cal. Sup. Ct. Aug. 29, 2000)

COORDINATION PROCEEDINGS SPECIAL TITLE (Rule..., 2000 WL 35568182...)

2000 WL 35568182 (Cal.Superior) (Trial Order)
Superior Court of California,
City of San Francisco.
San Francisco County

COORDINATION PROCEEDINGS SPECIAL TITLE (Rule 1550(b)) Microsoft I - V Cases.

No. J.C.C.P. 4106.
August 29, 2000.

Order Re Class Certification

[Stuart R. Pollak](#), Judge of the Superior Court.

This is a coordinated proceeding brought by plaintiffs as representatives of two purported classes of California indirect purchasers of software products produced by defendant Microsoft Corporation.

The operative complaint for all of the coordinated actions¹ alleges causes of action under the Cartwright Act ( Bus. & Prof. Code, § 16720 et seq.) and the Unfair Competition Act ( Bus. & Prof. Code, § 17200 et seq.). Plaintiffs allege that defendant engaged in numerous violations of these Acts in establishing and maintaining an illegal monopoly of the Intel-compatible personal computer markets for operating systems software and for word processing and spreadsheet applications software. Plaintiffs allege that Microsoft harmed California consumers by overcharging for its software as a result of the abuse of its monopoly power and by depriving consumers of other benefits that would have been derived from competition in those markets.

Plaintiffs seek to bring this action on behalf of California individuals and entities that purchased software programs indirectly from Microsoft. Specifically, plaintiffs request that two classes be certified:

(1) The “Windows and MS-DOS Operating System Software Class:” All persons or entities within the State of California who, on or after May 18, 1994, indirectly purchased “Microsoft Windows operating system software or MS-DOS operating system software” and who did not purchase it for the purpose of resale.

(2) The “Word and Excel Software Class:” All persons or entities within the State of California who, on or after May 18, 1994, indirectly purchased Microsoft “Word” word processing software and/or “Excel” spreadsheet software compatible with “Microsoft Windows operating system software or MS-DOS operating system software” and who did not purchase it for the purpose of resale.

Excluded from the class[es] are government entities, Microsoft officers and directors, subsidiaries in which Microsoft has greater than a 50 percent ownership interest and any judges or justices assigned to hear any aspect of this litigation. Also excluded are persons or entities who make their purchases after the date of notice to the class.²

Microsoft contends that the complexities of this case preclude common proof of the key issue of whether any illegal practices adversely impacted California consumers, and that certification is therefore inappropriate. “[S]hort of making an individual inquiry as to each proposed class member, [there is] no way of proving the key ‘fact of injury’ or ‘impact’ element in an antitrust class action: that the alleged monopolistic ‘overcharge’ actually worked a discernible, tangible impact on the vast majority of end-users in the proposed class. Nor could the amount of the alleged overcharge, if any, passed on to an end-user be estimated without individual investigation.” (Microsoft Corporation’s Memorandum of Points and Authorities in Support

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of Its Opposition to Plaintiffs' Renewed Motion for Class Certification ("Opp.") at p.3.)

While plaintiffs urge that "[t]here is nothing extraordinary about [this] motion" (Memorandum of Points and Authorities in Support of Plaintiffs' Renewed Motion for Class Certification ("Motion") at p. 1), the application for certification of a class in this case is hardly run of the mill. Unlike virtually all reported decisions in antitrust cases in which classes of indirect purchasers have been certified, plaintiffs do not base their claim for recovery on allegations that defendant committed a *per se* violation--a critical factor that would permit a classwide presumption of injury. Moreover, there undoubtedly is a basis for Microsoft's emphasis on the number of software programs it has marketed over the purported class period, the pricing differences that have existed over this period of more than six years, the rapid pace of change in the computer industry over this period, the varied channels through which its software has been distributed, and the critical fact that its software was frequently incorporated into personal computers and represented only a small fraction of the consumers' purchase price. These factors require the court to consider with utmost care the particular issues raised by the allegations and the way in which plaintiffs intend to meet their burden of proof. The question at this point, however, is not whether plaintiffs will be able to prove their case, but only whether their contentions can be evaluated in a manner that does not require consideration of so many individualized circumstances as to be completely impracticable.

A. Standard for Class Certification.

Class suits are authorized in California when "the question is one of a common or general interest, of many persons, or when the parties are numerous, and it is impracticable to bring them all before the court." ([Code Civ. Proc., § 382.](#)) A class should be certified when the party seeking certification has demonstrated the existence of an ascertainable class and a well-defined community of interest among the class members. ([Richmond v. Dart Indus., Inc.](#) (1981) 29 Cal.3d 462, 470, 174 Cal.Rptr. 515, 629 P.2d 23; see also [Daar v. Yellow Cab Co.](#) (1967) 67 Cal.2d 695, 704, 63 Cal.Rptr. 724, 433 P.2d 732.) The community of interest requirement embodies three factors: "(1) predominant common questions of law or fact; (2) class representatives with claims or defenses typical of the class; and (3) class representatives who can adequately represent the class." ([Linder v. Thrifty Oil Co.](#) (2000) 23 Cal.4th 429, 435 (citing [Richmond v. Dart Indus., Inc., supra](#), 29 Cal.3d at p. 470, 174 Cal.Rptr. 515, 629 P.2d 23.) In addition, the party seeking certification must establish that the class action is a superior method of adjudicating the matter. ([Reyes v. Board of Supervisors](#) (1987) 196 Cal.App.3d 1263, 1279-1280, 242 Cal.Rptr. 339.) In the absence of controlling state authority, California courts look to [Rule 23 of the Federal Rules of Civil Procedure](#) and to the federal case law interpreting this rule. ([Richmond v. Dart Indus., Inc., Supra](#), 29 Cal.3d at pp. 469-470, 174 Cal.Rptr. 515, 629 P.2d 23.)³

The party seeking certification of the class carries the burden of establishing that the requirements for certification are met. ([Richmond v. Dart Indus., Inc., supra](#), 29 Cal.3d at p. 470, 174 Cal.Rptr. 515, 629 P.2d 23.) Courts encourage the use of the class action to "prevent a failure of justice in our judicial system." ([Linder v. Thrifty Oil Co., supra](#), 23 Cal.4th at p. 434.) Consumers' individual damages frequently are insufficient to justify the costs of litigation, so that in the absence of class treatment, violations of law inflicting substantial damages in the aggregate would go unremedied. But to ensure that no party suffers a failure of justice, it is necessary to "carefully weigh respective benefits and burdens and to allow maintenance of the class action only where substantial benefits accrue both to litigants and the courts." ([Linder v. Thrifty Oil Co., supra](#), 23 Cal.4th at p. 435.)

In considering a class certification motion, the court accepts the facts alleged in the complaint as true. (See [Linder v. Thrifty Oil Co., supra](#), 23 Cal.4th at p. 443; [Blackie v. Barrack](#) (9th Cir.1975) 524 F.2d 891, 901, fn. 17.) The Supreme Court has recently emphasized that certification of a class is a procedural question that should not be conditioned upon a showing that the class claims are likely to succeed on the merits. ([Linder v. Thrifty Oil Co., supra](#), 23 Cal.4th at pp. 439-440, 443.) The Supreme Court also has repeated that courts should resolve any doubt as to whether to certify a class in

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favor of certification. (See, e.g., *Richmond v. Dart Indus., Inc.*, *supra*, 29 Cal.3d at pp. 473-475, 174 Cal.Rptr. 515, 629 P.2d 23; *La Sala v. American Savings & Loan Ass'n* (1971) 5 Cal.3d 864, 883, 97 Cal.Rptr. 849, 489 P.2d 1113; *Vasquez v. Superior Court* (1971) 4 Cal.3d 800, 807, 94 Cal.Rptr. 796, 484 P.2d 964.)

While issues affecting the merits may be enmeshed with class action requirements, the issue at this stage of the proceedings is only whether the matter is suitable for resolution on a classwide basis. (*Linder v. Thrifty Oil Co.*, *supra*, 23 Cal.4th at p.443.) Plaintiffs are not now required to prove their case. (See *id.* at p.438-39, 443; *Eisen v. Carlisle & Jacqueline* (1974) 417 U.S. 156, 177, 94 S.Ct. 2140, 40 L.Ed.2d 732; *In re Catfish Antitrust Litigation* (N.D.Miss.1993) 826 F.Supp. 1019, 1038-1039.) Rather, they are required to make a “threshold showing” that the antitrust violations, if proven, have had a common impact on the class. (*In re Catfish Antitrust Litigation*, *supra*, at pp. 1041-1042.) Plaintiffs are also required to advance a method for proving generalized damages on a classwide basis “not so insubstantial that it amount[s] to no method at all.” (*Id.*, at p. 1042.) In response to plaintiffs’ showing that all of the requirements for class certification have been met, Microsoft disputes only whether common questions of law or fact predominate.⁴

B. Indirect Purchaser Suits for Damages in California.

California is one of a minority of states that permits indirect purchasers to maintain antitrust suits for damages. Rejecting *Illinois Brick Co. v. Illinois* (1977) 431 U.S. 720, 97 S.Ct. 2061, 52 L.Ed.2d 707, in which the United States Supreme Court held that such suits could not be maintained under the federal Sherman Act, the California Legislature amended the Cartwright Act specifically to permit indirect purchaser actions under California law. (*Bus. & Prof. Code*, § 16750(a).) The California Supreme Court noted that this legislative action constituted an endorsement of Justice Brennan’s dissenting opinion in *Illinois Brick* and “a mandate to avoid unnecessary procedural barriers to indirect purchasers’ prosecution of California antitrust suits.” (*Union Carbide v. Superior Court* (1984) 36 Cal.3d 15, 21-22, 201 Cal.Rptr. 580, 679 P.2d 14.)

C. Common Questions of Law or Fact Predominate over Individual Questions.

Plaintiffs’ burden is to establish that common questions of law or fact predominate over individual issues. This inquiry “turns on an interpretation of substantive issues of antitrust law.” (*Rosack v. Volvo of America Corp.* (1982) 131 Cal.App.3d 741, 751, 182 Cal.Rptr. 800 (*Rosack*.)) Federal case law interpreting the Sherman and Clayton Acts is applicable to interpretation of California’s antitrust law. (*Ibid.*) To establish liability, plaintiffs must prove an antitrust violation and demonstrate that the class suffered injury or impact as a result of the violation. (*B.W.I. Custom Kitchen v. Owens-Illinois, Inc.* (1987) 191 Cal.App.3d 1341, 1350, 235 Cal.Rptr. 228 (*B.W.I. Custom Kitchen*).) For class certification purposes, plaintiffs may satisfy this requirement by making a “threshold showing that the antitrust violation, if proven, had a common impact on the class members.” (*In re Catfish Antitrust Litigation*, *supra*, 826 F.Supp. at pp. 1038-1039.) “If plaintiffs have stated claims of illegality and impact which can be proved predominantly with facts applicable to the class as a whole, rather than by a series of facts relevant to only individual or small groups of plaintiffs, then prosecution of this case as a class action is appropriate and desirable.” (*Rosack*, *supra*, 131 Cal.App.3d at p. 752, 182 Cal.Rptr. 800.) Plaintiffs’ proposed method for generalized proof of damages must not be “so insubstantial that it amount[s] to no method at all.” (*In re Catfish Antitrust Litigation*, *supra*, 826 F.Supp. at p. 1042.)

Plaintiffs frame the common questions presented by this action as follows:

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(1) whether Microsoft possesses monopoly power in the relevant computer software markets; (2) whether Microsoft has acquired, maintained and increased its market power through violations of the Cartwright Act and the Unfair Competition Act ([Bus. & Prof. Code §§ 16720, 16727 and 17200](#)); (3) whether Microsoft exploited its illegal monopoly to cause substantial harm to competition in the relevant markets; (4) whether Microsoft exploited its illegal monopoly to cause substantial harm to consumers by overcharging them for inferior products, suppressing innovation and denying consumers their freedom of choice in a competitive market; (5) whether Microsoft should be required to make full restitution for the harm it unlawfully inflicted upon consumers and the profit it unlawfully reaped from consumers; and (6) whether Microsoft should be enjoined from continuing its violations of law.

(Plaintiffs' Reply in Support of Renewed Motion for Class Certification ("Reply") at pp. 10-11.) The issues presented fall into three categories: (1) whether Microsoft violated California's antitrust law; (2) whether any such violation caused harm to the classes; and (3) what relief is appropriate.

1. Violation.

Plaintiffs allege numerous antitrust violations by Microsoft that had the purpose and effect of establishing and maintaining an illegal monopoly of the personal computer operating systems, word processing and spreadsheet software markets. (Compl. at ¶¶ 37, 38, 104-107.) Plaintiffs allege that Microsoft exploited its monopoly power to cause substantial harm to competition and to the ultimate consumers of Microsoft's products in California, including overcharges for the software programs at issue. (Compl. at ¶¶ 104, 105, 107.) Such conduct, if proven, violates the Cartwright Act, which prohibits combinations or conspiracies in restraint of trade. ([Bus. & Prof. Code, § 16720 et seq.](#))

As evidence of the substantiality of their claims and the susceptibility of these claims to classwide analysis, plaintiffs point to the Findings of Fact in the antitrust action brought by the United States against Microsoft. ([United States v. Microsoft Corp. \(D.D.C.1999\) 65 F.Supp.2d 1](#) [hereafter "Findings of Fact"]; see also [United States v. Microsoft Corp. \(D.D.C.2000\) 87 F.Supp.2d 30](#) [hereafter "Conclusions of Law"].) There, the District Court made detailed findings of various forms of anticompetitive conduct by Microsoft. Judge Jackson found that Microsoft engaged in anticompetitive conduct to protect Windows, its core asset, from competition (e.g. Findings of Fact ¶¶ 132, 194, 409-412; *see also* Conclusions of Law § I.2), including restrictions on personal computer manufacturers, internet access providers and internet content providers. (E.g. Findings of Fact ¶¶ 155, 203, 215, 221, 234, 235, 237, 242-336.) Judge Jackson found that Microsoft charged higher prices than it would have in a competitive environment, consistent with monopoly power (Findings of Fact ¶¶ 62, 63),⁶ and concluded that Microsoft's conduct had "harmed consumers in ways that are immediate and discernible." (Findings of Fact ¶ 409.)

Such Sherman Act violations also constitute violations of the Cartwright Act and violations of the Unfair Competition Act ([Quelimane Co. v. Stewart Title Guaranty Co. \(1998\) 19 Cal.4th 26, 42-43](#)), and will entail proof of the same conduct by Microsoft as to each class member. ([Rosack, supra, 131 Cal.App.3d at p. 752, 182 Cal.Rptr. 800](#); [In re Catfish Antitrust Litigation, supra, 826 F.Supp. at p. 1039](#).) Microsoft's actions in this regard are not differentiated with respect to individual consumers; the focus is squarely on Microsoft's conduct, not the conduct of individual class members. Thus, the proof required to demonstrate the "existence, implementation and effect" of the alleged unlawful conduct will require "a common thread of evidence" which will "correspond to evidence which otherwise would be introduced by absentee class members." ([B.W.I. Custom Kitchen, supra, 191 Cal.App.3d at p. 1349, 235 Cal.Rptr. 228](#) [quoting [In re Sugar Indus. Antitrust Litigation \(E.D.Pa.1976\) 73 F.R.D. 322, 345](#)]; [In re Flat Glass Antitrust Litigation \(W.D.Pa.1999\) 191 F.R.D. 472](#),

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484.) Plaintiffs have made a sufficient “threshold showing” that the issues of fact and law regarding Microsoft’s alleged violations of the Cartwright Act and the Unfair Competition Act are subject to common proof.

2. Fact of Injury.

Plaintiffs must also demonstrate that whether consumers suffered harm as a result of Microsoft’s anticompetitive conduct is also capable of proof on a classwide basis. (*B.W.I. Custom Kitchen, supra*, 191 Cal.App.3d at p. 1350, 235 Cal.Rptr. 228.)⁷ “[A]n antitrust plaintiff’s ‘burden of proving the fact of damage...is satisfied by its proof of some damage flowing from the unlawful conspiracy; inquiry beyond this minimum point goes only to the amount and not the fact of damage.’ ” (*Ibid.* [citing *Zenith Corp. v. Hazeltine* (1969) 395 U.S. 100, 114, fn. 9].) Plaintiffs contend that Microsoft harmed the class by charging supracompetitive prices for its software. Plaintiffs must, therefore, make a “threshold showing” that proof of the overcharge is common to the class.

There is considerable authority for the proposition that in a case alleging price fixing the fact of injury may be determined on a classwide basis. (See, e.g., *B.W.I. Custom Kitchen, supra*, 191 Cal.App.3d 1341, 235 Cal.Rptr. 228; *Rosack, supra*, 131 Cal.App.3d 741, 182 Cal.Rptr. 800; *In re Catfish Antitrust Litigation, supra*, 826 F.Supp. 1019; *In re Sugar Antitrust Litigation, supra*, 73 F.R.D. 322.) Because price fixing is a *per se* violation of antitrust law, a presumption of harm arises from proof of such a violation. (*B.W.I. Custom Kitchen, supra*, at pp. 1350-1353, 235 Cal.Rptr. 228; *Rosack, supra*, at pp. 753-754, 182 Cal.Rptr. 800.) “It has been held that impact will be presumed once a plaintiff demonstrates the existence of an unlawful conspiracy that had the effect of stabilizing, maintaining or establishing product prices beyond competitive levels.” (*In re Sugar Indus. Antitrust Litigation, supra*, at p. 347.) A *per se* violation raises a presumption of harm because conduct such as a conspiracy to fix prices has the sole purpose of artificially raising the price of the item. It follows that consumers of the product pay more than they would in a competitive market even if the prices charged to direct purchasers vary. (*B.W.I. Custom Kitchen, supra*, at pp. 1350-1351, 235 Cal.Rptr. 228.) Thus, a plaintiff need not provide evidence of harm to direct purchasers above and beyond establishing “the existence of an unlawful conspiracy that had the effect of stabilizing, maintaining, or establishing product prices beyond competitive levels.” (*In re sugar Indus. Antitrust Litigation, supra*, at p. 347.)

Holding monopoly power, however, is not itself a violation of any antitrust provision. Whether particular practices engaged in to acquire, maintain or extend such power constitute violations must be evaluated under the rule of reason. (*Bert G. Gianelli Distrib. Co. v. Beck & Co.* (1985) 172 Cal.App.3d 1020, 1047-1048, 219 Cal.Rptr. 203; *Standard Oil Co. v. United States* (1910) 221 U.S. 1, 61-62, 31 S.Ct. 502, 55 L.Ed. 619.) Some practices that flow from the existence of monopoly power may benefit rather than harm consumers, so that injury may not be presumed simply from proof that the defendant engaged in the conduct in question. (*Standard Oil Co. v. United States, supra*, 221 U.S. at pp. 61-62.) Here, Microsoft makes exactly that contention: that the various practices that are challenged--such as preventing other products from being used with its operating systems and bundling its internet browser with its operating system--have been of great benefit to the public by enhancing product standardization and increasing the ease of computer use and internet access.

But while the presence of these additional issues in a monopolization case such as this may preclude any presumption of harm, as in a price-fixing case, the existence of these issues does not necessarily mean that common issues do not predominate. Without regard to the possibility that some of the relevant issues in this case may be conclusively determined by the final outcome in the Government’s action against Microsoft, remaining issues concerning the legality of defendant’s practices are issues common to all members of the classes plaintiffs seek to certify. As discussed in section C.1 above, the fundamental and predicate issues as to whether defendant violated the Cartwright Act are not differentiated among individual consumers. In this respect, the situation is no different from a case involving an alleged conspiracy that would constitute a *per se* violation of the statute.

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If it should be determined that defendant's practices unlawfully elevated prices to direct purchasers of Microsoft's software, the complexities of the marketplace to which defendant refers will affect the ability to analyze whether, and the extent to which, these higher prices were passed on to consumers. However, once the existence of unlawfully inflated prices at the direct purchaser level has been established, the difficulties of determining whether the price increase was absorbed by those direct purchasers or passed on to successive purchasers in the chain of distribution are no greater in a monopolization case than in a *per se* price-fixing case. There is no ascertainable difference between the analysis of the impact of the abuse of a monopoly and of price fixing once the overcharge to direct purchasers has been established, and in response to the court's inquiry at oral argument Microsoft offered none. The starting point in both situations is artificially high prices set in an anticompetitive market. The same economic models and analyses that have been accepted for purposes of tracing a supracompetitive price that results from a price fixing conspiracy are relevant and applicable to trace the pass-through resulting from monopoly abuse.

Unlike the conclusion reached by the Supreme Court in *Illinois Brick* and by the courts of some other states, the California courts have made clear that the difficulties in tracing the pass-through of artificially inflated prices do not necessarily create insuperable obstacles to classwide analysis and to class certification. "In certifying a plaintiff class, the courts have found it appropriate to look past surface distinctions among the products purchased by class members or the marketing mechanisms involved when allegations of anticompetitive behavior embracing all of the various products and distribution patterns have been credibly pleaded. [Citation omitted.] Identical products, uniform prices, and unitary distribution patterns are not indispensable for class certification in this context." ( *B.W.I. Custom Kitchen, supra*, 191 Cal.App.3d at p. 1350, 235 Cal.Rptr. 228 [quoting *Shelter Realty Corp. v. Allied Maintenance Corp.* (S.D.N.Y.1977) 75 F.R.D. 34, 37];  *Rosack, supra*, 131 Cal.App.3d at p. 757, 182 Cal.Rptr. 800 [same].) "[C]ontentions of infinite diversity of product, marketing practices, and pricing have been made in numerous cases and rejected." ( *Rosack, supra*, 131 Cal.App.3d at p. 755, 182 Cal.Rptr. 800 [quoting  *In re Folding Carton Antitrust Litigation* (N.D.Ill.1977) 75 F.R.D. 727, 734].) "It should also be emphasized that courts have applied these principles to markets, such as this one, characterized by individually negotiated prices, varying profit margins, and intense competition." ( *B.W.I. Custom Kitchen, supra*, at p. 1351, 235 Cal.Rptr. 228.)

Nonetheless, defendant argues that the complexity and changing nature of the software markets over the past six years have been so great as to render classwide analysis "impossible" in this case. (Opp.  at p. 1, 235 Cal.Rptr. 228.) Focusing almost exclusively on the market for operating systems software, defendant emphasizes that over the class period it marketed a progression of product "families"--from MS DOS to the most current Windows NT Workstation system. The variety of illegal practices in which defendant allegedly engaged necessarily affected the price defendant was able to and did charge at different times and for different products. If defendant engaged in predatory pricing, the price to some purchasers presumably would have been less than a competitively determined price, so that some class members may have benefited from the practice, rather than having been damaged by it. Because of the high level of competition among computer manufacturers ("original equipment manufacturers" or "OEMs"), each OEM that purchased software directly from Microsoft made its own pricing decisions and therefore each may have absorbed rather than passed on a different portion of any excess in the price paid to Microsoft. Because the software represents only a small percentage of the cost of the computer, and because there are many other factors which may inhibit passing on price changes (such as "focal point" pricing and "menu costs"), whether, and the extent to which, any given OEM passed on the excess will differ from case to case. The amount passed through by distributors or retailers purchasing from the OEMs, or purchasing directly from Microsoft, may also vary, so that the fact, much less the amount, of any overcharge reaching a consumer will be a function of so many variables, defendant argues, that the impact of any violation cannot possibly be considered collectively. In the words of Microsoft's economist, Professor Jerry A. Hausman, "any analysis of whether an overcharge may have been passed on to an eventual final purchaser would require an evaluation of a large number of individual-specific facts that essentially will amount to an individualized inquiry for each final purchaser." (Declaration of Jerry A. Hausman ("Hausman Decl.") ¶ 32.)

Such a broad statement proves too much. If true, it would invalidate the entire study of microeconomics. In his Findings of Fact, Judge Jackson concluded that Microsoft's conduct had "harmed consumers in ways that are immediate and discernible." (Findings of Fact ¶ 409.) To demonstrate that impact on consumers can be proven on a non-individualized and classwide

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basis, plaintiffs rely heavily on the expert opinion of Professor Jeffrey K. MacKie-Mason, an economist. Accepting the allegations in the Complaint and the Findings of Fact, and based upon his knowledge of the industry, Professor MacKie-Mason opined that plaintiffs could demonstrate common impact on the classes “by showing that, as a result of Microsoft’s monopoly power (derived from or maintained by the anticompetitive conduct alleged) consumers (1) were charged supra-competitive prices for [the relevant software] and (2) experienced less choice and innovation in [the relevant software markets] than they would have enjoyed in a competitive market.” (Declaration of Jeffrey K. MacKie-Mason in Support of Plaintiffs’ Renewed Motion for Class Certification (“MacKie-Mason Decl.”) ¶ 6(a), (c).) “When a monopolist sets prices above competitive levels to its distributors, it generally results that all customers suffer harm.” (Declaration of Jeffrey K. MacKie-Mason in Support of Plaintiffs’ Reply re Renewed Motion for Class Certification (“MacKie-Mason Reply Decl.”) ¶ 5.) Summarizing his conclusions, Professor MacKie-Mason stated:

As is well known in economic theory and practice, at least some of the overcharge will be passed on by distributors to end consumers. When the distribution markets are highly competitive, as they are here, all or nearly all of the overcharge will be passed through to ultimate consumers.... Both of Microsoft’s experts also agree upon the economic phenomenon of cost pass through, and how it works in competitive markets. This general phenomenon of cost pass through is well established in antitrust law and economics as well.”

(MacKie-Mason Reply Decl. ¶ 6.)

Professor MacKie-Mason described several recognized methods to estimate what Microsoft’s prices to its direct purchasers would have been in a hypothetical “but for” world in which Microsoft had not engaged in the allegedly anticompetitive conduct. These include the use of “yardstick” prices based on the prices of products when the markets were more competitive or the prices of similar goods sold in more competitive markets; the comparative margin method (calculating the price at which Microsoft’s margin on a product would equal the average margin of other software manufacturers); and constructing models of equilibrium in the relevant markets. (MacKie-Mason Decl. ¶¶ 28-36.) He further described two methods to measure the extent to which particular increased costs were passed on to final purchasers, both based on equilibrium models of distribution channels. (MacKie-Mason Decl. ¶¶ 38-40.)

Professor MacKie-Mason did not commit himself to the use of any one or more of these approaches, nor did he make the necessary calculations or attempt to prove that any of these methods ultimately will be able to support plaintiffs’ burden of proof at trial. Nonetheless, his declarations contain a good bit more than a plea to “trust me,” as the defendant would characterize his testimony. (Opp.  at p. 3, 235 Cal.Rptr. 228.)

In addition to proposing several methodologies shown to be widely accepted within the profession, plaintiffs submitted several published works by prominent economists and consumer groups that have conducted empirical analyses to demonstrate general harm to consumers as a result of Microsoft’s conduct. (Hall, *Toward A Quantification of the Effects of Microsoft’s Conduct* (2000) American Economic Review 90; Fisher & Rubinfeld, *United States v. Microsoft: An Economic Analysis* in Did Microsoft Harm Consumers? Two Opposing Views (AEI-Brookings Joint Center for Regulatory Studies 2000); Fisher & Rubinfeld, *Misconceptions, Misdirection, and Mistakes* in Did Microsoft Harm Consumers? Two Opposing Views (AEI-Brookings Joint Center for Regulatory Studies 2000); Consumer Federation of America, Media Access Project, U.S. Public Interest Research Group, The Consumer Cost of the Microsoft Monopoly: \$10 Billion of Overcharges and Counting (Jan. 1999).) Moreover, the opposing experts agree that equilibrium economic models can be used to calculate damages in antitrust cases. According to the defense expert, Professor Hausman:

Economists have developed various theoretical models of competition in markets with limited numbers of sellers. These models are based on a series of strong simplifying assumptions. They can provide useful

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bases for suggestive theoretical analyses, but they do not provide reliable bases for calculating damages *unless carefully designed and calibrated to fit the actual conditions of the market in question.*

(Hausman Decl. ¶ 125 (emphasis added).)

Professor Hausman asserts that none of the methods proposed by Professor MacKie-Mason will work because none of them “accounts for the real world complexities of the products and the distribution chains at issue.” (Hausman Decl. ¶ 113.) However, the experts agree on the importance of product differentiation in reaching dependable conclusions (Hausman Decl. ¶ 126; MacKie-Mason Decl. ¶ 108.), but, not surprisingly, disagree over the extent to which Professor MacKie-Mason’s anticipated models will reflect reality. (See, e.g., [Hausman Decl. at pp. 43-52, 235 Cal.Rptr. 228](#); MacKie-Mason Decl. [at pp. 38-52, 235 Cal.Rptr. 228](#).) The question at this stage is not whether plaintiffs will be able to carry their burden of proving that their experts’ analyses are reliable, but whether it appears that the differences between the experts can be intelligently presented and evaluated within the framework of a class action. On a motion for class certification, it is inappropriate to resolve a “battle of the experts.” ([In re Catfish Antitrust Litigation, supra, 826 F.Supp. at p. 1042](#)) “Whether or not [plaintiff’s expert] is correct in his assessment of common impact/injury is for the trier of fact to decide at the proper time. [Citations omitted.] For now, the court is persuaded that for the purposes of a class certification motion, plaintiffs have made [the required] threshold showing....” (*Ibid.*) The court is similarly persuaded here.

It may be, as defendant has argued, that closer examination of the facts will disclose that not all class members were harmed by Microsoft’s practices.⁸ However, plaintiffs need not prove that each and every class member paid a supracompetitive price for the relevant software products. As explained in *Rosack*, “[t]he courts have rejected the notion that each member of the purported class must prove that he or she absorbed at least some portion of the overcharges in order to establish liability. [Citations omitted] ‘[C]lass certification does not require that common questions be completely dispositive... as to all potential members of the class. [Citations omitted.] The fact that certain members of the class may not have been injured at all does not defeat class certification. [Citations omitted.]’” ([Rosack, supra, 131 Cal.App.3d at pp. 753-754, 182 Cal.Rptr. 800](#).) Similarly, the *B.W.I. Custom Kitchen* court pointed out that “[e]ven if it were shown that certain class members escaped having to pay any of the overcharge..., the fact remains that in the vast majority of cases at least a portion of the illegal overcharge was passed on by the independent distributors to class members in the form of higher prices.” ([B.W.I. Custom Kitchen, supra, 191 Cal.App.3d at p. 1353, 235 Cal.Rptr. 228](#).) whether that is true in this case will depend upon an evaluation of the evidence at trial.

Defendant is correct that the multiple products embraced within each of the two proposed classes, the multiple distribution channels, and the extraordinary rate at which changes have occurred in the relevant markets over the six-year class period will complicate the analysis of the impact of any illegal practices in which Microsoft is found to have engaged. The trier of fact undoubtedly will be required to do more than make a single determination of whether any damages were incurred by the respective classes over the six-year period. However, plaintiffs advise that their evidence and expert studies will be presented in a manner that will permit, at a minimum, annual comparisons of prices paid by consumers for particular software products with the prices that would have prevailed in the hypothetical “but for” world in the absence of the unlawful practices. Moreover, since the relevant comparison is not between actual prices and prices in a perfectly competitive market, or even between actual prices and prices lawfully obtained in a monopoly market, plaintiffs’ evidence will need to establish “the price increment caused by the anticompetitive conduct that originated or augmented the monopolist’s control over the market.” ([Berkey Photo, Inc. v. Eastman Kodak Co. \(2d Cir.1979\) 603 F.2d 263, 297](#).) The task is formidable, but not impossible. As the case proceeds towards trial, careful consideration will have to be given to the possibility of creating subclasses, bifurcating issues, making special findings, or using other techniques that may facilitate the presentation and consideration of the relevant evidence. At this point, the court is not persuaded that a comprehensible analysis of these issues cannot be made within the context of properly managed trial proceedings.

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3. Calculation of Damages.

Plaintiffs must also meet their burden of demonstrating that the amount of damages is susceptible to classwide proof. With respect to calculating damages once liability has been established, individual issues will not bar certification of a class. (*B.W.I. Custom Kitchen, supra*, 191 Cal.App.3d at p. 1354, 235 Cal.Rptr. 228; *Rosack, supra*, 131 Cal.App.3d at p. 761, 182 Cal.Rptr. 800.) “[I]t has been recognized consistently that differences among potential class members concerning damages do not preclude class treatment so long as common questions regarding conspiracy and impact allegations predominate.” (*Rosack, supra*, at p. 761, 182 Cal.Rptr. 800.). Courts recognize a somewhat relaxed standard of proof once the antitrust violation and resulting injury have been proven. (*In re Catfish Antitrust Litigation, supra*, 826 F.Supp. at p. 1042.) This is the logical result of an inability to ascertain exactly what “plaintiff’s position would have been in the absence of defendant’s antitrust violation.” (*Ibid.*) “Hence, the willingness to accept some uncertainty stems from a simple, equitable notion that the wrongdoer should not be allowed to profit by an insistence upon an unattainable standard of proof.” (*Id.*, at pp. 1042-1043; see also *Bigelow v. RKO Radio Pictures, Inc.* (1946) 327 U.S. 251, 264, 66 S.Ct. 574, 90 L.Ed. 652.)

The basic measure of damages for overcharges resulting from Microsoft’s alleged anticompetitive conduct is the difference between the price paid by a class member for a particular product and the price that would have been paid absent the alleged anticompetitive conduct. (See *In re Catfish Antitrust Litigation, supra*, 826 F.Supp. at p. 1043; MacKie-Mason Decl. ¶¶ 25, 40.) To determine this amount, as discussed in section C.2 above, it is of course necessary to determine both the amount of the overcharge by Microsoft and the amount of such overcharge passed through to the consumer. Total classwide damages are the sum of the overcharges on all software programs sold to class members during the class period. (MacKie-Mason Decl. ¶ 40.)

Plaintiffs need not present a method to calculate each class member’s damage individually. California courts permit calculation of damages in the aggregate for a class and do not require summing all individual claims. (*Daar v. Yellow Cab Co., Supra*, 67 Cal.2d at pp. 706, 714, 716, 63 Cal.Rptr. 724, 433 P.2d 732; *Bruno v. Superior Court* (1981) 127 Cal.App.3d 120, 128-129 & fn. 4, 179 Cal.Rptr. 342.) A reasonable basis for computing damages is permissible, even if it involves approximation or estimation. (*Suburban Mobile Homes, Inc. v. AMFAC Communities, Inc.* (1980) 101 Cal.App.3d 532, 545, 161 Cal.Rptr. 811; *Bigelow, supra*, 327 U.S. at pp. 264-265.) Other courts in antitrust proceedings have found similar approaches to be sufficiently viable for purposes of class certification. (See, e.g., *In re Catfish Antitrust Litigation, supra*, 826 F.Supp. at p. 1043; *In re Domestic Air Transportation Antitrust Litigation* (N.D. Ga. 1991) 137 F.R.D. 677, 692; *In re Corrugated Container Antitrust Litigation* (S.D.Tex.1978) 80 F.R.D. 244, 251.) Moreover, it is not necessary that plaintiffs demonstrate to a certainty that their proposed methods will succeed, and it would be improper for the court to make a determination as to the likely success of plaintiffs’ proposed methods. (*In re Domestic Air Transportation Antitrust Litigation, supra*, at p. 693; *In re Flat Glass Antitrust Litigation, supra*, 191 F.R.D. at p. 487.)

The method of calculating the amount of any recovery that will be received by each class member and the method of distributing damages to class members are different questions altogether that need not be addressed at this point, and which the parties have not argued. Suffice it to say that there is no reason to presume that conventional techniques for notifying class members of their right to submit claims and for submitting and processing claims will not be feasible in this litigation. Nor is there any reason to assume that the amounts to which individual class members may be entitled will be insufficient to justify the effort and expense of a claim procedure. Moreover, as noted by plaintiffs, fluid class recovery is also a possibility. (*Bruno, supra*, 127 Cal.App.3d at p. 135, 179 Cal.Rptr. 342; *Kraus v. Trinity Management Services, Inc.* (2000) 23 Cal.4th 116, 119-120.) Should problems in calculating damages appear to outweigh the benefits of class treatment, the court may reconsider its certification order and vacate or amend the certification. (*B.W.I. Custom Kitchen, supra*, 191 Cal.App.3d at p. 1348, 235 Cal.Rptr. 228 [citations omitted].)

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D. A Class Action Is a Superior Method of Adjudicating the Matter.

Finally, plaintiffs must demonstrate that a class action would be of substantial benefit to the litigants and the court. (See  *Blue Chip Stamps v. Superior Court* (1976) 18 Cal.3d 381, 385, 134 Cal.Rptr. 393, 556 P.2d 755.) This requirement incorporates the superiority standard of  Rule 23 of the Federal Rules of Civil Procedure. (*Schneider v. Vennard* (1986) 183 Cal.App.3d 1340, 1347, 228 Cal.Rptr. 800.) The matters pertinent to this determination include:

- (A) the interest of members of the class in individually controlling the prosecution or defense of separate actions;
- (B) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class;
- (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum;
- (D) the difficulties likely to be encountered in the management of a class action.

 Fed. Rules Civ. Proc., Rule 23(b)(3), 28 U.S.C.) The various indirect purchaser claims filed in California against Microsoft already have been consolidated in this court, which is specifically called upon to utilize innovative methods to manage complex cases as part of the Judicial Council's Complex Civil Litigation pilot program. (See also  *B.W.I. Custom Kitchen, supra*, 191 Cal.App.3d at p. 1355, 235 Cal.Rptr. 228 [calling upon courts to adopt innovative methods for handling indirect purchaser class actions].)

This case involves a very large number of claimants with relatively small amounts at stake. Most consumers have little incentive to litigate independently since the costs of litigation undoubtedly would overwhelm their potential recovery. "The problems which arise in the management of a class action involving numerous small claims do not justify a judicial policy that would permit the defendant to retain the benefits of its wrongful conduct and to continue that conduct with impunity."

 *Linder v. Thrifty Oil Co., supra*, 23 Cal.4th at p. 446.) Moreover, the potential recovery here is not so insignificant to warrant the assumption that individual consumers will not be motivated to claim any recovery to which they may be entitled, or that a favorable outcome would benefit only the attorneys involved. And, to the extent that purchasers of large quantities of Microsoft software should elect to pursue their individual claims, denying class treatment could result in repetitious litigation and inconsistent adjudication of similar issues and claims. ( *Richmond v. Dart Indus., Inc., supra*, 29 Cal.3d at p. 469, 174 Cal.Rptr. 515, 629 P.2d 23.) Under the circumstances, the superiority of a class action is apparent.

CONCLUSION

In keeping with the Supreme Court's mandate, this court must "avoid interpreting procedural requirements in such a way as 'would thwart the legislative intent ... to retain the availability of indirect-purchaser suits as a viable and effective means of enforcing California's antitrust laws.'" ( *B.W.I. Custom Kitchen, supra*, 191 Cal.App.3d at p. 1355, 235 Cal.Rptr. 228 [quoting  *Union Carbide Corp. v. Superior Court, supra*, 36 Cal.3d at p. 21].) The court finds that the proposed classes are ascertainable, that the classes are sufficiently numerous, that the named representatives' claims are typical of those of the classes and that the interests of the classes will be fairly and adequately represented. In addition, common questions of fact or law predominate and a class action is the superior method for adjudicating the matter. Accordingly, the two proposed classes will be certified, and the litigation will proceed as a class action.

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Counsel should confer concerning the method of giving notice to the classes and the content of the notice, and be prepared to discuss these issues at the status conference scheduled for October 4, 2000.

Dated: August 29, 2000

<<signature>>

STUART R. POLLAK

Judge of the Superior Court

Footnotes

¹ The Amended Complaint for Violations of California Business and Professions Code §§ 16720 and 17200 Seeking Damages, Restitution and Injunctive Relief, Class Action, filed March 19, 1999 in *Lingo v. Microsoft Corporation*, San Francisco Superior Court No. 301357 (hereafter “Complaint”).

² Microsoft notes that because it does not actually “sell” its software to anyone (rather, it “licenses” its products), it is technically incorrect to refer to putative class members as indirect “purchasers.” However, for the sake of simplicity, the court will also adopt plaintiffs’ use of the widely recognized terminology. However, the term “licensed” should be inserted in the definition of the classes to be certified.

³ Rule 23 of the Federal Rules of Civil Procedure requires that plaintiff show common questions of fact or law, numerosity of the class, typicality of the named plaintiff’s claim and adequacy of representation. In addition, plaintiff must show that the common questions of law or fact predominate over questions affecting only individual class members and that the class action is superior to other methods for fairly and efficiently resolving the dispute. (Fed. Rules Civ. Proc., Rule 23(a), (b)(3), 28 U.S.C.; *B.W.I. Custom Kitchen v. Owens-Illinois, Inc.*, (1987) 191 Cal.App.3d 1341, 1347, fn. 5, 235 Cal.Rptr. 228.)

⁴ Microsoft does not seem to contest that the proposed classes are ascertainable. Whether a class is ascertainable depends on the clarity of the class definition, the numerosity of the putative class and the means available to identify potential class members. (*Reyes v. Board of Supervisors, supra*, 196 Cal.App.3d at p. 1974, 242 Cal.Rptr. 592.) The class definitions make clear that any California consumer of the software at issue who purchased the product(s) for his, her or its own use and not for resale within the class period is a member of the class. The definitions also make clear who is excluded from the classes. Moreover, according to declarations submitted with the moving papers, the named plaintiffs who seek to represent one or both classes are themselves members of one or both of the classes. The numerosity requirement also is not disputed and is satisfied because the class members are so numerous that it is “impracticable to bring them all before the court.” (Code Civ. Proc., § 382.) There is no predetermined number of class members necessary as a matter of law for the maintenance of a class action. (*Hebbard v. Colgrave* (1972) 28 Cal.App.3d 1017, 105 Cal.Rptr. 172 (not inappropriate to certify class involving a minimum of 28 members); *Clothesrigger, Inc. v. GTE Corp.* (1987) 191 Cal.App.3d 605, 236 Cal.Rptr. 605 (mere size of proposed class numbering over one million members did not make proposed class action unmanageable.) Here plaintiffs allege there are “clearly millions of class members.” (Motion at p. 19, 236 Cal.Rptr. 605.) The typicality requirement is satisfied if the representative plaintiff’s claim “has the essential characteristics common to the claims of the class.” (*In re Flat Glass Antitrust Litigation* (1999) 191 F.R.D. 472, 479.) The named plaintiffs’ claims here, that they paid illegal overcharges due to defendant’s antitrust violations, are identical to those of the class, and are, therefore, typical of those of the class.

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Again, the parties do not take issue with the adequacy of representation requirement, which is met by (1) retaining class counsel competent to handle the litigation; and (2) ensuring that the class representatives' interests are not antagonistic to those of the class. In approving plaintiffs' proposed organization of counsel, this court found plaintiffs' counsel to be well qualified to conduct this litigation. (See Pretrial Order No.1, filed Mar. 9, 2000, and supporting documentation filed by plaintiffs in support thereof.) The named plaintiffs' claims arise through the same set of facts as do those of the class and their claimed injuries are the same. Through declarations, the named plaintiffs attest to their ability and willingness to prosecute the litigation and protect the interests of the class.

- 5 Plaintiffs allege that Microsoft controls approximately 90% of the operating systems, word processing and spreadsheet software markets. (Compl. ¶¶ 31, 34, 36.)
- 6 In further support of their motion, plaintiffs submitted the opinion of Professor David J. Farber describing the nature of the competition that would have existed absent Microsoft's alleged anticompetitive conduct (the "but for" world) and opining that pricing for operating systems and applications software would have been lower had Microsoft not engaged in such conduct. (Declaration of David J. Farber in Support of Plaintiffs' Renewed Motion for Class Certification ("Farber Decl.") ¶¶ 34, 57.)
- 7 The parties acknowledge the distinction between the fact of harm or impact, on the one hand, and actual damages, on the other. "Fact of damage pertains to the existence of injury, as a predicate to liability; actual damages involve the quantum of injury, and relate to the appropriate measure of individual relief." ( *B.W.I. Custom Kitchen, supra*, 191 Cal.App.3d at p. 1350, fn. 7, 235 Cal.Rptr. 228 [citation omitted].)
- 8 Some skepticism is warranted as to the extent to which defendant will be able to prove its assertion in this regard. Microsoft contends, for example, that its conduct benefited rather than harmed consumers because consumers received Microsoft's Web browser, Internet Explorer, at "no charge." Judge Jackson found that Microsoft's practice of bundling its Web browser with Windows was designed to harm the ability of Netscape's Navigator Web browser to compete and caused harm to consumers. (Findings of Fact ¶¶ 143, 155-160, 166-168, 171-177; Conclusions of Law ¶¶ at pp. 38-40, 42-43, 235 Cal.Rptr. 228.) Moreover, as Professor Mackie-Mason explained, the effect of an overcharge is not cured by the marketing strategy; "buy three tires; get the fourth tire free." (MacKie-Mason Reply Decl. ¶ 23.)

Exhibit 10

Order (clarifying CMO No. 1), *In re Nat'l Prescription Opiate Litig.*,
No. 1:17-md-02804 [Dkt. No. 371] (N.D. Ohio May 3, 2018)

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION) CASE NO. 1:17-MD-2804
)
) JUDGE POLSTER
)
) ORDER

The Court enters this Order to clarify a provision contained in Case Management Order Number 1 (docket no. 232). Paragraph 6.b of CMO-1 states:

Amendment of Pleadings and Addition of Parties. In cases other than those mentioned in paragraphs 2 and 3, Plaintiffs shall file any amended pleading, including any amendment to add a party to a case, **no later than Friday, May 25, 2018**. After that date, no complaint shall be amended by Plaintiffs to add a party or otherwise, absent leave of Court or stipulation of the parties. The deadline for Defendants to add a party without leave of Court shall be **45 days before the close of fact discovery** applicable to a particular case.

Counsel for plaintiffs have contacted the Court asking whether paragraph 6.b applies to every case transferred to the MDL and whether there will be any other opportunities to amend. The answer is that, if a plaintiff in an MDL case wants to file an amended complaint *without* leave of Court, it must do so by May 25, 2018. Thereafter, all cases not designated in paragraphs 2 or 3 of CMO-1 are stayed until further order of a Court. If a case is later designated as a bellwether for motion practice or trial, a separate CMO will be entered that will provide for another opportunity to amend. And, plaintiffs retain the right to move to file further amended pleadings if deemed appropriate, such as

because additional defendants were identified by ARCOS data.

This clarification does not relieve plaintiffs from any other obligations set out in CMO-1, such as timely submission of fact sheets.

/s/ *Dan Aaron Polster*

DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE

Dated: May 3, 2018

Exhibit 11

Order Approving Stipulation by and Between the Debtors, the Official Committee of Unsecured Creditors, and the Hospital Claimants Establishing Class Claims Procedures, *In re Insys Therapeutics, Inc.*, No. 19-11292 [Dkt. No. 949] (Bankr. D. Del. Dec. 4, 2019)

IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE

-----x
In re : Chapter 11
:
INSYS THERAPEUTICS, INC., et al. : Case No. 19-11292 (KG)
:
Debtors.¹ : Jointly Administered
:
: Re: Docket No. 946
-----x

**ORDER APPROVING STIPULATION BY AND BETWEEN THE
DEBTORS, THE OFFICIAL COMMITTEE OF UNSECURED CREDITORS,
AND THE HOSPITAL CLAIMANTS ESTABLISHING CLASS CLAIMS PROCEDURES**

Upon consideration of the *Stipulation By and Between the Debtors, the Official Committee of Unsecured Creditors, and the Hospital Claimants Establishing Class Claims Procedures* (the “**Stipulation**”),² a copy of which is attached hereto as Exhibit 1; and the Court having jurisdiction to consider the Stipulation pursuant to 28 U.S.C. § 1334; and approval of the Stipulation being a core matter pursuant to 28 U.S.C. § 157(b)(2); and sufficient notice of the Hospital Class Claimants’ Motion having been provided; and it appearing that no other notice of the same is required under the circumstances; and good and sufficient cause appearing therefor,

IT IS HEREBY ORDERED THAT:

1. The Stipulation is hereby approved.
2. Immediately upon the entry of this Order, the Stipulation shall become effective and the Hospital Class Claimants’ Motion shall be deemed withdrawn without prejudice.

¹ The Debtors in these chapter 11 cases, along with the last four digits of each Debtor’s federal tax identification number, as applicable, are: Insys Therapeutics, Inc. (7886); IC Operations, LLC (9659); Insys Development Company, Inc. (3020); Insys Manufacturing, LLC (0789); Insys Pharma, Inc. (9410); IPSC, LLC (6577); and IPT 355, LLC (0155). The Debtors’ mailing address is 410 S. Benson Lane, Chandler, Arizona 85224.

² Capitalized terms used but not defined in this Order have the meanings used in the Stipulation.

3. The Parties are authorized to take any and all actions reasonably necessary to implement and effectuate the terms of the Stipulation.

4. This Court retains jurisdiction over all matters arising from or related to the implementation or interpretation of this Order.

Dated: December 4th, 2019
Wilmington, Delaware

RLF1 21965742v.4


KEVIN GROSS
UNITED STATES BANKRUPTCY JUDGE

EXHIBIT 1

Stipulation

**IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE**

-----x
In re : Chapter 11
: Case No. 19-11292 (KG)
INSYS THERAPEUTICS, INC., et al., :
: Jointly Administered
Debtors.¹ :
: Re: Docket No. _____
-----x

**STIPULATION BY AND BETWEEN THE DEBTORS,
THE OFFICIAL COMMITTEE OF UNSECURED CREDITORS, AND
THE HOSPITAL CLAIMANTS ESTABLISHING CLASS CLAIMS PROCEDURES**

This stipulation (the “**Stipulation**”) is made and entered into by and between Insys Therapeutics, Inc. and its affiliated debtors, as debtors and debtors in possession (collectively, the “**Debtors**”), the official committee of unsecured creditors (the “**Committee**”), and the Hospital Claimants² (collectively, the “**Parties**”), by and through their respective undersigned counsel.

RECITALS

WHEREAS, on June 10, 2019 (the “**Petition Date**”), each of the Debtors commenced with the United States Bankruptcy Court for the District of Delaware (the “**Court**”) a voluntary case under chapter 11 of title 11 of the United States Code, 11 U.S.C. §§ 101-1532 (the “**Bankruptcy Code**”);

WHEREAS, on August 7, 2019, the Hospital Claimants filed the *Motion by Hospital Class Action Claimants Pursuant to Fed. R. Bankr. P. 9014 and 7023 to Make Federal Rule of Civil*

¹ The Debtors in these chapter 11 cases, along with the last four digits of each Debtor’s federal tax identification number, as applicable, are: Insys Therapeutics, Inc. (7886); IC Operations, LLC (9659); Insys Development Company, Inc. (3020); Insys Manufacturing, LLC (0789); Insys Pharma, Inc. (9410); IPSC, LLC (6577); and IPT 355, LLC (0155). The Debtors’ mailing address is 410 S. Benson Lane, Chandler, Arizona 85224.

² The “**Hospital Claimants**” are: Infirmary Health Hospitals, Inc., Mobile, Alabama, St. Vincent Charity Medical Center (at times d/b/a Rosary Hall), Cleveland, Ohio, Southwest Mississippi Regional Medical Center, McComb, Mississippi, and Monroe County Healthcare Authority, d/b/a Monroe County Hospital, Monroeville, Alabama.

Procedure 23 Applicable to These Proceedings and to Permit the Filing of a Class Proof of Claim
[Docket No. 404] (the “**Hospital Class Claimants’ Motion**”).

NOW THEREFORE, THE PARTIES, BY AND THROUGH THEIR RESPECTIVE
UNDERSIGNED COUNSEL, HEREBY STIPULATE AND AGREE AS FOLLOWS:

1. The above recitals are fully incorporated herein and made an express part of this Stipulation.
2. Upon approval of this Stipulation by the Court, (a) the Hospital Class Claimants’ Motion shall be deemed withdrawn without prejudice, (b) the procedures attached hereto as **Exhibit 1-A** (as may be amended or supplemented by agreement of the Parties in connection with confirmation of the Proposed Plan (as defined below), the “**Hospital Class Claims Procedures**”) with respect to holders of claims represented by the Hospital Claimants under the terms of the Hospital Class Claims Procedures and the Proposed Plan (the “**Hospital Class**”) shall become binding upon the Parties hereto in these chapter 11 cases, and (c) the Hospital Claimants’ Proof of Claims numbered 10027 filed on August 7, 2019 shall be deemed to be filed on behalf of the Hospital Class (the “**Hospital Class Claim**”), and shall be the Hospital Class Claim with respect to which the Debtors, or any successor thereto, will make distributions under the Proposed Plan, if confirmed.
3. Subject to approval by the Court, the Parties consent, and waive any right to object, to incorporation of the terms of the Hospital Class Claims Procedures into the *Second Amended Joint Chapter 11 Plan of Liquidation of Insys Therapeutics, Inc. and Its Affiliated Debtors* [Docket No. 928] (as may be amended or modified from time to time, the “**Proposed Plan**”) and the disclosure statement related thereto [Docket No. 929] (as may be amended or modified from

time to time, the “**Proposed Disclosure Statement**”), and the Parties agree to be bound by such terms.

4. The Hospital Claimants may, upon written notice to the counsel for the Debtors and the Committee, terminate this Stipulation if any of the following shall occur: (i) the Proposed Plan (subject to non-material modifications) is not confirmed by the Court through and including the date of the expiration of the period during which the Debtors exclusively may file a plan (as the same may be extended from time to time); (ii) these chapter 11 cases shall be converted to cases under another chapter of the Bankruptcy Code; (iii) a trustee shall be appointed in these cases; or (iv) these cases shall be dismissed.

5. The Debtors, or any successor to the Debtors, may terminate this Stipulation on written notice to the Hospital Claimants if any of the following shall occur: (i) the Proposed Plan (subject to non-material modifications) is not confirmed by the Court through and including the date of the expiration of the period during which the Debtors exclusively may file a plan (as the same may be extended from time to time); (ii) these chapter 11 cases shall be converted to cases under another chapter of the Bankruptcy Code; (iii) a trustee shall be appointed in these cases; (iv) these cases shall be dismissed; or (v) if the Hospital Claimants fail to comply with any requirement of the Hospital Class Claims Procedures.

6. If this Stipulation is terminated, (a) the designation of the Hospital Class Claim as a Claim filed on behalf of the Hospital Class shall be rescinded and the Hospital Class Claim and any other Proof of Claim filed in connection herewith shall be treated as filed solely on behalf of the Hospital Claimants, and (b) the Hospital Claimants shall be relieved of any further obligations under the Hospital Class Claims Procedures.

7. This Stipulation constitutes the entire agreement between the Parties and supersedes all prior agreements and understandings, both written and oral, between the Parties with respect to the subject matter hereof and, except as otherwise expressly provided herein, is not intended to confer upon any other person any rights or remedies hereunder.

8. Except as expressly set forth in this Stipulation or the Hospital Class Claims Procedures, nothing contained herein shall be an admission or waiver of the substantive or procedural rights, remedies, claims, or defenses of any of the parties in these chapter 11 cases, whether at law or equity.

9. Each of the Parties shall bear its own attorneys' fees and costs with respect to the execution and delivery of this Stipulation and the Hospital Class Claims Procedures; *provided, however,* that the allowed attorneys' fees and costs of the Committee shall be paid pursuant to applicable provisions of the Bankruptcy Code and orders of the Court.

10. This Stipulation may be executed in counterparts, any of which may be transmitted by facsimile or electronic mail, and each of which shall be deemed an original and all of which together shall constitute one and the same instrument.

11. This Stipulation and the Hospital Class Claims Procedures may not be amended without the express written consent of all Parties hereto.

12. It is acknowledged that each Party has participated in and jointly consented to the drafting of this Stipulation and the Hospital Class Claims Procedures and that any claimed ambiguity shall not be construed for or against either Party on account of such drafting.

13. The Court shall retain jurisdiction over any and all disputes or other matters arising under or otherwise relating to this Stipulation.

Dated: December 3, 2019
Wilmington, Delaware

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Attorneys for the Hospital Claimants

EXHIBIT 1-A

Procedures

Proposed Class Claim Procedures

Hospital Class Claim

1. The Hospital Class includes all hospitals in the United States, other than those owned by the federal government, which treated patients with opioid conditions. “Patients with opioid conditions” are defined as patients with opioid overdose; patients with opioid addiction; babies born opioid addicted; opioid users committed to mental health treatment programs; and opioid users with pretextual excuses for obtaining opioids.
2. No Distributions¹ will be made to the Hospital Class Representative(s) (the trustee(s) to be appointed pursuant to the Plan) on the Hospital Class Claim under the Plan, and instead, will be held by the Liquidating Trustee for the benefit of the Hospital Class, until Hospital Class Allocation Plan (defined below) has been approved by the Bankruptcy Court.
3. Within six months of the Effective Date of the Plan, or within such other time as agreed to by the Hospital Class Representative(s) and the Liquidating Trustee or as otherwise ordered by the Bankruptcy Court, the Hospital Class Representative(s) will develop and propose an allocation plan based on the damages analysis of a Hospital Class Representative’s expert’s analysis and empirical observation (the “**Hospital Allocation Plan**”). The Hospital Class Representative(s) will file a motion and proposed order with the Bankruptcy Court seeking (a) approval of a notice and claims administration procedure and (b) approval of the Hospital Allocation Plan, which will include provisions for the establishment of the Hospital Escrow Account (described below).
4. If the Hospital Class Representative(s) determines, after consultation with the Liquidating Trustee and after finalization of the Hospital Allocation Plan, that paying available Distributions to Class Participants would be uneconomical based on the amount of available Distributions, the Hospital Class Representative(s) will establish an escrow account to hold Distributions (the “**Hospital Escrow Account**”) until such time as the funds available to the Hospital Class Representative(s) are sufficient, in a Hospital Class Representative’s sole discretion, to warrant distribution to Hospital Class participants. Upon the establishment of the Hospital Escrow Account, the Liquidating Trustee will make Distributions under the Plan into the Hospital Escrow Account. The Hospital Class Representative(s) will provide a status report to the Liquidating Trustee every 90 days reflecting the status of the Hospital Escrow Account until such time as the amount of Distributions paid under the Plan into the Hospital Escrow Account has been paid to Hospital Class participants.
5. The Hospital Class Representative(s) will retain a notice provider and claims administrator using a competitive bidding process.
6. If Distributions paid into the Hospital Escrow Account, if any, have not been distributed to Hospital Class Participants within 2 years of the date of payment into the Hospital Escrow Account, such Distributions will be returned to the ILT Trust as Available Cash for further distribution under the Plan on account of Allowed Claims other than the Hospital Class Claim.

¹ Capitalized terms used but not defined herein shall have the meanings ascribed to such terms in the *Second Amended Joint Chapter 11 Plan of Liquidation of Insys Therapeutics, Inc. and Its Affiliated Debtors* [Docket No. 928] (as may be amended or modified from time to time, the “**Plan**”).

Exhibit 12

Order, *In re Opioid Litig.*, No. 19-C-9000
(Cir. Ct. Kanawha Cty., W. Va. Feb. 19, 2020)



IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

IN RE: OPIOID LITIGATION

CIVIL ACTION NO. 19-C-9000

THIS DOCUMENT APPLIES TO:

West Virginia University Hospitals, Inc., et al.

v.

Purdue Pharma L.P., et al.

Civil Action Nos. 19-C-69 MSH to
19-C-88 MSH and 19-C-134 MSH
to 19-C-139 MSH

ORDER

Pending before the Court are numerous motions to dismiss Plaintiffs' Amended Complaint pursuant to Rule 12(b)(6) of the West Virginia Rules of Civil Procedure:¹

1. *Defendants Rite Aid of Maryland, Inc., CVS Health Corporation, CVS Pharmacy, Inc., CVS Indiana, LLC, The Kroger Co., Kroger Limited Partnership, II, Walgreen Co., Walmart, Inc., and Wal-Mart Stores East, LP's Motion to Dismiss Plaintiffs' Amended Complaint* (Transaction ID 64447991);
2. *Defendants Watson Laboratories, Inc., Actavis Pharma, Inc. F/K/A Watson Pharma, Inc., and Actavis LLC's Motion to Dismiss Plaintiffs' First Amended Complaint* (Transaction ID 64448957);
3. *Amneal Pharmaceuticals LLC's Supplemental Motion to Dismiss Plaintiffs' First Amended Complaint* (Transaction ID 64450443);
4. *Defendants Amerisourcebergen Drug Corporation and Cardinal Health, Inc.'s Motion to Dismiss Complaint* (Transaction ID 64450128);
5. *Manufacturer Defendants' Motion to Dismiss Plaintiffs' First Amended Complaint* (Transaction ID 64449553);²
6. *Defendant, Anda, Inc.'s Motion to Dismiss* (Transaction ID 64450613);

¹ Plaintiff, Appalachian Regional Healthcare, Inc., has voluntarily dismissed without prejudice, its claims against Defendants for violation of Kentucky's Consumer Protection Act, K.R.S. 367.110, *et seq.* *Notice of Partial Voluntary Dismissal* (Transaction ID 64667947).

² This motion is brought by the following Defendants (collectively, the "Manufacturer Defendants"): Amneal Pharmaceuticals, LLC; Amneal Pharmaceuticals, Inc.; Teva Pharmaceuticals Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Assertio Therapeutics, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals Inc.; Mallinckrodt, LLC; Mallinckrodt PLC; SpecGX, LLC; Allergan PLC; Watson Laboratories, Inc.; Actavis LLC; Actavis Pharma, Inc; and Noramco, Inc.

7. *Defendant, Henry Schein, Inc.'s Motion to Dismiss Plaintiffs' First Amended Complaint* (Transaction ID 64450801);
8. *Defendants Teva Pharmaceuticals USA, Inc. and Cephalon, Inc.'s Motion to Dismiss Plaintiffs' First Amended Complaint* (Transaction ID 64450805);
9. *Mallinckrodt LLC and Specgx LLC's Supplemental Motion to Dismiss Plaintiffs' First Amended Complaint* (Transaction ID 64450907); and
10. *Abbott Defendants' Motion to Dismiss Plaintiffs' First Amended Complaint* (Transaction ID 64450925).

All of these motions have been fully briefed by the parties.³

As explained by the Court in *John W. Lodge Distributing Co., Inc. v. Texaco, Inc.*, 161 W. Va. 603, 604-606, 245 S.E.2d 157, 158-159 (1978):

The purpose of a motion under Rule 12(b)(6) of the West Virginia Rules of Civil Procedure is to test the formal sufficiency of the complaint. For purposes of the motion to dismiss, the complaint is construed in the light most favorable to plaintiff, and its allegations are to be taken as true. Since common law demurrs have been abolished, pleadings are now liberally construed so as to do substantial justice. W.Va. R.C.P. 8(f). The policy of the rule is thus to decide cases upon their merits, and if the complaint states a claim upon which relief can be granted under any legal theory, a motion under Rule 12(b)(6) must be denied.

* * *

In view of the liberal policy of the rules of pleading with regard to the construction of plaintiff's complaint, and in view of the policy of the rules favoring the determination of actions on the merits, the motion to dismiss for failure to state a claim should be viewed with disfavor and rarely granted. The standard which plaintiff must meet to overcome a Rule 12(b)(6) motion is a liberal standard, and few complaints fail to meet it. The plaintiff's burden in resisting a motion to dismiss is a relatively light one. *Williams v. Wheeling Steel Corp.*, 266 F.Supp. 651 (N.D.W.Va.1967)

³To the extent any Defendants have incorporated by reference or rely on arguments previously stated in their motions to dismiss filed in *Brooke County Commission, et al. v. Purdue Pharma L.P., et al.*, Civil Action Nos. 17-C-248 MSH through 17-C-255 MSH ("Brooke County"), and *Monongalia County Commission, et al. v. Purdue Pharma L.P., et al.*, Civil Action Nos. 18-C-222 MSH and 18-C-233 MSH through 18-C-236 MSH ("Monongalia County"), the Court incorporates by reference the Orders denying motions to dismiss, entered on December 28, 2018, in *Brooke Co.*, petitions for writ of prohibition refused, June 6, 2019, Orders, State ex. rel. Cardinal Health v. Honorable David W. Hummel, Jr., et al., No. 19-0204, State ex. rel. Purdue Pharma, et al. v. Honorable David W. Hummel, Jr., et al., No. 19-0205, State ex rel. AmerisourceBergen Drug Corporation, et al. v. Honorable David W. Hummel, Jr., et al., No. 19-0210; and the Orders denying motions to dismiss entered on October 31, 2019, in *Monongalia County*, petition for writ of prohibition refused, February 3, 2020, Order, State ex. rel. AmerisourceBergen Drug Corporation, et al. v. Honorable Alan D. Moats, et al., No. 19-1051.

A trial court considering a motion to dismiss under Rule 12(b)(6) must “liberally construe the complaint so as to do substantial justice.” *Cantley v. Lincoln Co. Comm’n.*, 221 W. Va. 468, 470, 655 S.E.2d 490, 492 (2007) and West Virginia Rule of Civil Procedure, Rule 8(f). “The trial court, in appraising the sufficiency of a complaint on a Rule 12(b)(6) motion, should not dismiss the complaint unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.” *Id.* at Syl. pt. 2, quoting Syl. pt. 3, *Chapman v. Kane Transfer Company*, W.Va., 236 S.E.2d 207 (1977).

Having reviewed the above-listed Motions to Dismiss and all of the briefing, and having conferred with one another to ensure uniformity of their decision, as contemplated by *Rule 26.07(a)* of the *West Virginia Trial Court Rules*, the Presiding Judges unanimously **FIND** that, construing the Amended Complaint in the light most favorable to Plaintiffs, and taking its allegations as true, the Amended Complaint sufficiently states claims upon which relief can be granted, and the Defendants have not demonstrated that Plaintiffs can prove no set of facts in support of their claims which would entitle them to relief. Accordingly, the above-listed Motions to Dismiss are **DENIED**. All exceptions and objections are noted and preserved for the record.

A copy of this Order has been electronically served on all counsel of record this day via File & ServeXpress.

It is so **ORDERED**.

ENTERED: February 19, 2020.

/s/ Alan D. Moats
Lead Presiding Judge
Opioid Litigation

Exhibit 13

Ruling, *Tucson Med. Ctr. v. Purdue Pharma, L.P., et al.*, No. C20184991
(Ariz. Super. Ct., Pima Cty., Sept. 16, 2019)

FILED
GARY L. HARRISON
CLERK, SUPERIOR COURT
9/16/2019 6:45:18 PM

ARIZONA SUPERIOR COURT, PIMA COUNTY

HON. JANET C. BOSTWICK

CASE NO. C20184991

DATE: September 16, 2019

TUCSON MEDICAL CENTER

Plaintiff

VS.

PURDUE PHARMA L.P., et al.

Defendants

R U L I N G

IN CHAMBERS RE: DEFENDANTS' MOTIONS TO DISMISS

This ruling addresses the Manufacturing Defendants Joint Motion to Dismiss; the Distributor Defendants Joint Motion to Dismiss; the Actavis Parties and Watson Laboratories, Inc. Motion to Dismiss; the Cephalon, Inc. and Teva Pharmaceuticals, Inc. Motion to Dismiss; the Janssen Pharmaceuticals, Inc. and Johnson & Johnson Motion to Dismiss; and the Mallinckrodt LLC and SpecGx LLC Motion to Dismiss.

Without repeating the full record reviewed by the Court or relying on matters extrinsic to the Complaint, the Court concludes that Plaintiff Tucson Medical Center has adequately alleged potentially cognizable causes of action at a notice pleading standard under Rule 12(b)(6), Arizona Rules of Civil Procedure, as described below. For reasons set forth in briefing and incorporated by reference, Defendants' motions to dismiss must be denied.

Arizona Rule 12(b)(6)

“Arizona follows a notice pleading standard.” *Coleman v. City of Mesa*, 230 Ariz. 352, 356 (2012); *Cullen v. Auto-Owners Ins. Co.*, 218 Ariz. 417, 419 (2008). The intent is to “give the opponent fair notice of the nature and basis of the claim and indicate generally the type of litigation involved.” *Cullen*, 218 Ariz. at 419. As a general policy matter, motions to dismiss are not favored, especially if based on pleading insufficiencies. *State ex. rel. Corbin v. Pickrell*, 136 Ariz. 589, 594 (1983); *Cagle v. Carr*, 101 Ariz. 225, 227 (1966); *see generally Rowland v. Kellogg Brown & Root, Inc.*, 10 Ariz. 530, 533 (App. 2005) (finding complaint sufficient despite “numerous technical deficiencies in the document”). Dismissal is permitted only if a plaintiff would not be entitled to relief under “any interpretation of the facts susceptible of proof.” *Cullen*, 218 Ariz. at 420; *Fidelity Sec. Life Ins. Co. v. State Dept. of Ins.*, 191 Ariz. 222, 224 (1998). A court accepts all material allegations as true and views facts in the light most favorable to the opposing party but will not accept legal conclusions or hypothetical facts. *Cullen*, 218 Ariz. at 419-20; *Jeter v. Mayo Clinic Ariz.*, 211 Ariz. 386, 389 (App. 2005).

Brandy Brothers

Judicial Administrative Assistant

UNDER ADVISEMENT RULING

Page 2

Date: September 16, 2019

Case No.: C20184991

Sufficiency of Claims Pled

The narrow question presented by a motion to dismiss for failure to state a claim is whether facts alleged are sufficient “to warrant allowing the [plaintiff] to attempt to prove [its] case.” *Coleman*, 230 Ariz. at 363. A motion to dismiss is not a procedure for resolving disputes about the facts or merits of a case. *Id.* at 363. Evidence may or may not later support a pled claim, but that is a separate question beyond Rule 12(b)(6). See *Swiekiewicz v Sorema N.A.*, 534 U.S 506, 512 (recognizing “simplified notice pleading standard [for complaints] relies on liberal discovery rules and summary judgment motions to define disputed facts and issues and dispose of unmeritorious claims”). With this standard in mind, the Court has reviewed and considered each argument Defendants raise even if not specifically addressed in this ruling, and concluded that Arizona Rule 12(b)(6) pleading requirements are met. The issues may not, in this Court’s view, be resolved at the pleading stage where the question is notice and all factual allegations are presumed true. The Court recognizes, of course, that when the record is further developed such defenses remain as potential summary judgment issues.

Fraud. Rule 9(b), Arizona Rules of Civil Procedure, requires circumstances constituting fraud to be pled with particularity. See *Comerica Bank v. Mahmoodi*, 224 Ariz. 289, 291-92 (App. 2010). The purpose of Rule 9(b) is to eliminate surprise. *Pruitt v. Pavelin*, 141 Ariz. 195, 206 (App. 1984). “[M]agic language is not necessary in pleading fraud, as long as the pleading, considered as a whole, can be construed to plead the nine elements.” *Hall v. Romero*, 141 Ariz. 120, 124 (App. 1984); see also *Parks v. Macro-Dynamics, Inc.*, 121 Ariz. 517, 520 (App. 1979). A fraud complaint as a whole should assert a misrepresentation made with knowledge of falsity or ignorance of its truth to induce the hearer, ignorant of the falsity, to rely, resulting in damages. E.g., *Dawson v. Withycombe*, 216 Ariz. 84, 96 (App. 2007).

Considering the Complaint as a whole, combining allegations attributed to Defendants by name and to all Manufacturing or Distributor Defendants, the Court finds the necessary particularity for the fraud claims to proceed. As to RICO fraud, the allegations may be read broadly, as RICO is “liberally construed to effect its remedial purposes” and the right to relief for private parties injured by racketeering activity. *Sedima SPRL v. Imrex Co., Inc.*, 473 U.S. 479, 497-98 (quoting *U.S. v. Turkette*, 451 U.S. 576, 586-87, Pub. L. No. 91-452, §904(a), 84 Stat. 947, Organized Crime Control Act of 1970). And for all fraud-based claims, Plaintiffs do allege various misrepresentations by Defendants inducing reliance and damages. Disclosure and discovery are needed to develop the claims, but the basic allegations allow notice and meet Rule 9(b) purposes. Defendants do not suggest specificity of the pleading leaves them unsure of whether to admit or deny a fraud allegation.

Public Nuisance. The critical inquiry in a public nuisance case is whether continuing conduct of a party contrary to law involves a “significant interference with public health.” Restatement (Second) of Torts § 812 B (2). Plaintiff so alleges, raising a possible nuisance claim, including special injury different from the general public due to the hospital’s unique role and costs in treating and fighting opioid addiction. See, e.g., *Hopi Tribe v. Ariz. Snowbowl Resort Ltd. Partnership*, 430 Ariz. 362, 363-64 (2018); Restatement (Second) of Torts § 812 C comment h (pecuniary loss to the plaintiff resulting from the public nuisance “is normally a different kind of harm from that suffered by the general public”); see also Restatement (Second) of Torts § 812 B, comment h

Brandy Brothers

Judicial Administrative Assistant

UNDER ADVISEMENT RULING

Page 3

Date: September 16, 2019

Case No.: C20184991

(public nuisance “does not necessarily involve interference with use and enjoyment of land”). These allegations are assumed true for Rule 12(b)(6) purposes. *Cullen* at 419. The public nuisance theory is unique in this case but is adequately pled and not precluded simply because it is novel or yet untested under Arizona law.

Unjust Enrichment. Unless the relationship of the parties is governed by contract, a party may generally allege unjust enrichment as an alternative claim if it fits the facts, though it does not permit double recovery. *Brooks v. Valley Nat'l Bank*, 113 Ariz. 169, 174 (1976); *see also Adelman v. Christy*, 90 F. Supp. 2d 1034, 1045-46 (D. Ariz. 2000). Plaintiff has sufficiently pled unjust enrichment, including asserted connection between the alleged enrichment and impoverishment. Dismissal would be premature at this stage of this case.

Proximate Cause and Derivative Injuries. The Court concludes that the causation and derivative injury issues Defendants raise amount to matters of proof, not pleading. Plaintiff does allege proximate cause and direct harm to TMC as well as derivative patient costs. If direct harm is debatable or proximate cause is interrupted by other causal links are not Rule 12(b)(6) questions. Again, Plaintiff's allegations must be assumed true.

Statutes of Limitation. Time-barred claims are often subject to dismissal at the pleading stage, but in this case questions of notice, knowledge and tolling raise issues inappropriate to address on a Rule 12(b)(6) basis. The limitations defenses raise questions for summary judgment, not dismissal for failure to state a claim.

Preemption/Generic Labeling. Defendants, particularly the Actavis Generic Entities, invoke *Mensing* federal preemption for claims that a generic manufacturer breached a duty to warn. *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011); *Mutual Pharms. Co. v. Bartlett*, 570 U.S. 472 (2013); *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378 (6th Cir. 2014). Due to the “sameness” constraint on generic drug manufacturers, state law cannot impose a duty to alter FDA-approved pharmaceutical labeling in conflict with federal law. These Defendants reason that all causes of action against them are, at their core, failure to warn claims and are preempted. Plaintiff maintains that it has made no failure to warn claims and that it is not seeking to change FDA-approved labels.

The nature of a claim and allegations made determine preemption. In *Strayhorn*, for example, claims based on knowing disclosure of false or misleading information about drugs, failure to adequately inform doctors about the risks associated with drugs, and failure to use reasonable care to provide warnings to the public were preempted. *Id.* at 385. Preemption would apply similarly to such claims against generic entities in this case. But which claims are necessarily preempted, whether such causes of action are preempted in full or can survive on other grounds, and whether amendment of the Complaint (which is liberally allowed) could partially address these issues is not clear on the present record. The Court requests additional briefing from Plaintiff and the Actavis Generic Entities on these preemption issues, as ordered below.

Conclusion

The Complaint sufficiently states causes of action at a notice pleading level under Arizona law and survives Defendants' motions to dismiss.

Brandy Brothers

Judicial Administrative Assistant

UNDER ADVISEMENT RULING

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Orders

Therefore,

IT IS ORDERED that Plaintiff and the Actavis Generic Entities provide supplemental simultaneous briefing on the generic manufacturer preemption issues raised in this ruling by October 1, 2019;

IT IS FURTHER ORDERED that Defendants Johnson & Johnson and Janssen Pharmaceutical, Inc. may, at their option, join in or file supplemental briefing on their separate preemption arguments by October 1, 2019.

IT IS FURTHER ORDERED that Defendants' Motions to Dismiss are otherwise denied.



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UNDER ADVISEMENT RULING

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Date: September 16, 2019

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Exhibit 14

Southwest Miss. Reg'l Med. Ctr., et al. v. AmerisourceBergen Drug Corp., et al,
No. 1:17-op-45175 [Dkt. No. 1] (N.D. Ohio, Nov. 30, 2017)

**THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF MISSISSIPPI
NORTHERN DIVISION
WESTERN**

SOUTHWEST MISSISSIPPI REGIONAL MEDICAL CENTER; INFIRMARY HEALTH HOSPITALS, INC., a corporation; MONROE COUNTY HEALTHCARE AUTHORITY, a corporation, d/b/a MONROE COUNTY HOSPITAL, a corporation; on behalf of themselves and all others similarly situated,

Plaintiffs,

AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH, INC.; McKESSON CORPORATION; PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; NORAMCO, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC f/k/a ACTAVIS PLS; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC;

CASE NO.: 5 :17-CV-145-KS-MTP

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

ACTAVIS PHARMA, INC. f/k/a
WATSON PHARMA, INC.;
MALLINCKRODT PLC and
MALLINCKRODT LLC.,

Defendants.

CLASS ACTION COMPLAINT

Plaintiffs Southwest Mississippi Regional Medical Center, Infirmary Health Hospitals, Inc., and Monroe County Healthcare Authority, d/b/a Monroe County Hospital, bring this Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceutical Industries, LTD.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis PLS; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Mallinckrodt plc; Mallinckrodt LLC; McKesson Corporation; Cardinal Health, Inc.; and AmerisourceBergen Drug Corporation (collectively “Defendants”) and allege as follows:

I. INTRODUCTION

1. The United States is in the midst of an opioid epidemic caused by Defendants’ unlawful marketing, sales, and distribution of prescription opioids¹ that has resulted in addiction, criminal activity, serious health issues, and loss of life.

¹ As used herein, the term “opioid” refers to the entire family of opiate drugs including natural, synthetic, and semi-synthetic opiates.

2. Plaintiffs bring this civil action to recover monetary losses that have been incurred as a direct and proximate result of Defendants' false, deceptive, and unfair marketing and/or unlawful diversion of prescription opioids. Such economic damages were foreseeable to Defendants and were sustained because of Defendants' unlawful actions and omissions.

3. Opioid analgesics are widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national epidemic of opioid overdose deaths and addictions.²

4. The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."³

5. Plaintiffs bring this suit against the manufacturers of prescription opioids. The manufacturers aggressively pushed highly addictive, dangerous opioids, falsely representing to doctors that patients would only rarely succumb to drug addiction. These pharmaceutical companies aggressively advertised to and persuaded doctors to prescribe highly addictive, dangerous opioids, and turned patients into drug addicts for their own corporate profit. Such actions were unlawful.

6. Plaintiffs also bring this suit against the wholesale distributors of these highly addictive drugs. The distributors and manufacturers unlawfully breached their legal duties under federal law to monitor, detect, investigate, refuse, and report suspicious orders of prescription opiates.

² See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain-Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

³ See Robert M. Califf et al., A Proactive Response to Prescription Opioid Abuse, 374 N. Eng. J. Med. 1480 (2016).

II. PARTIES

A. PLAINTIFFS

7. Plaintiff Infirmary Health Hospitals, Inc., is a private non-profit corporation organized under the laws of the State of Alabama, with its principal place of business in Alabama.

8. Plaintiff Monroe County Healthcare Authority, d/b/a Monroe County Hospital, is a public corporation organized under the laws of the State of Alabama, with its principal place of business in Alabama.

9. Plaintiff Southwest Mississippi Regional Medical Center is a public non-profit corporation organized under the laws of the State of Mississippi, with its principal place of business in Mississippi.

B. DEFENDANTS

1. Manufacturer Defendants

10. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. The Manufacturer Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty prevent diversion and report suspicious orders.

11. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. None of its partners are citizens of the State of Mississippi. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and THE

PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, “Purdue”).

12. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States. OxyContin is Purdue’s best-selling opioid. Since 2009, Purdue’s annual nationwide sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

13. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania.

14. TEVA PHARMACEUTICAL INDUSTRIES, LTD. (“Teva Ltd.”) is an Israeli corporation with its principal place of business in Petach Tikva, Israel. In 2011, Teva Ltd. Acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. (“Teva USA”) is a Delaware corporation which is a wholly owned subsidiary of Teva Ltd. In Pennsylvania. Teva USA acquired Cephalon in October of 2011.

15. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the United States. Actiq has been approved by the FDA only for the “management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain.”⁴ Fentora has been approved by the FDA only for the “management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant

⁴ *Highlights of Prescribing information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII (2009)*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf.

to around-the-clock opioid therapy for their underlying persistent cancer pain.”⁵ In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay \$425 million.⁶

16. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October of 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its “specialty medicines” division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

17. All of Cephalon’s promotional websites, including those for Actiq and Fentora, display Teva Ltd.’s logo.⁷ Teva Ltd.’s financial reports list Cephalon’s and Teva USA’s sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to “the inclusion of a full year of Cephalon’s specialty sales,” including *inter alia* sales of Fentora®.⁸ Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon

⁵ *Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII (2011)*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf.

⁶ Press Release, U.S. Dep’t of Justice, Biopharmaceutical Company, Cephalon, to Pay \$425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), <https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html>.

⁷ E.g., ACTIQ, <http://www.actiq.com/> (displaying logo at bottom-left) (last visited Aug. 21, 2017).

⁸ Teva Ltd., Annual Report (Form 20-F) 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf

and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon."

18. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. NORAMCO, INC. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July of 2016. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Noramco, and J&J are referred to as "Janssen."

19. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta

(tapentadol) and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

20. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Health Solutions, Inc. and Endo Pharmaceuticals Inc. are referred to as “Endo.”

21. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydome, in the United States. Opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion in 2012. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo’s total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

22. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired ALLERGAN PLC in March 2015, and the combined company changed its name to ALLERGAN PLC in January 2013. Before that, WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then ACTAVIS PLC in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of ALLERGAN PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business

in New Jersey and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by ALLERGAN PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, ALLERGAN PLC exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. ALLERGAN PLC, ACTAVIS PLC, ACTAVIS, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "Actavis."

23. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

24. MALLINCKRODT, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. MALLINCKRODT, LLC is a limited liability company organized and existing under the laws of the State of Delaware. Mallinckrodt, LLC has no members that are citizens of the State of Mississippi and is a wholly owned subsidiary of Mallinckrodt, plc. Mallinckrodt, plc and Mallinckrodt, LLC are referred to as "Mallinckrodt."

25. Mallinckrodt manufactures, markets, and sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers. In July of 2017 Mallinckrodt agreed to pay \$35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.

2. Distributor Defendants

26. The Distributor Defendants also are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal law. Plaintiffs allege the unlawful conduct by the Distributor Defendants is responsible for the volume of prescription opioids plaguing the United States.

27. McKESSON CORPORATION (“McKesson”) is a Delaware corporation, with its principal place of business located in San Francisco, California. McKesson distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states.

28. CARDINAL HEALTH, INC. (“Cardinal”) is an Ohio corporation with its principal place of business located in Dublin, Ohio. Cardinal distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states.

29. AMERISOURCEBERGEN DRUG CORPORATION (“AmerisourceBergen”) is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. AmerisourceBergen distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states.

III. JURISDICTION & VENUE

30. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 based upon the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.* (“RICO”). This Court has supplemental jurisdiction over Plaintiffs’ state law claims

pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiffs' federal claims that they form part of the same case or controversy.

31. This Court independently has subject matter jurisdiction over Plaintiffs' state law claims under 28 U.S.C. § 1332(d)(2)(A), because the matter in controversy, the aggregated claims of the individual Class members, exceeds the sum of five million dollars, exclusive of interest and costs, and Plaintiffs Infirmary Health Hospitals, Inc., Monroe County Healthcare Authority, Southwest Mississippi Regional Medical Center, and Warren General Hospital, members of the proposed Class, are citizens of states different from several of the Defendants. Under 28 U.S.C. § 1332(d)(5), there are more than 100 members of the proposed class.

32. This Court has personal jurisdiction over Defendants because all the Defendants purposefully conduct substantial business in this State and in this judicial district.

33. This Court also has personal jurisdiction over all of the Defendants under 18 U.S.C. 1965(b). This Court may exercise nation-wide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiffs demonstrate national contacts. Here, the interests of justice require that Plaintiffs be allowed to bring all members of the nationwide RICO enterprise before the court in a single trial. *See, e.g., Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc.*, 23 F.Supp.2d 796 (1998) (citing *LaSalle National Bank v. Arroyo Office Plaza, Ltd.*, 1988 WL 23824, *3 (N.D. Ill. Mar 10, 1988); *Butcher's Union Local No. 498 v. SDC Invest., Inc.*, 788 F.2d 535, 539 (9thCir. 1986)).

34. Venue is proper in this District under 28 U.S.C. § 1391(b)(2), because Plaintiff Southwest Mississippi Regional Medical Center is domiciled in this judicial district, because a substantial part of the events and omissions giving rise to Plaintiffs' claims occurred in this judicial district, and under 28 U.S.C. § (b)(1) and § (c)(2), because all the Defendants are subject to

personal jurisdiction in this state and in this judicial district, such that Defendants are deemed to reside in this state and in this judicial district.

IV. FACTUAL BACKGROUND

C. THE OPIOID EPIDEMIC

3. The National Opioid Epidemic.

35. The past two decades have been characterized by increasing abuse and diversion of prescription drugs, including opioid medications, in the United States.⁹

36. Prescription opioids have become widely prescribed. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.¹⁰

37. By 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention, declared prescription painkiller overdoses at epidemic levels. The News Release noted:

- a. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.
- b. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).
- c. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.
- d. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription painkillers non-medically

⁹ See Richard C. Dart et al, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).

¹⁰ Katherine M. Keyes et al., *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, 104 Am. J. Pub. Health e52 (2014).

according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.

- e. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.
- f. Almost 5,500 people start to misuse prescription painkillers every day.¹¹

38. The number of annual opioid prescriptions written in the United States is now roughly equal to the number of adults in the population.¹²

39. Many Americans are now addicted to prescription opioids, and the number of deaths due to prescription opioid overdose is unacceptable. In 2016, drug overdoses killed roughly 64,000 people in the United States, an increase of more than 22 percent over the 52,404 drug deaths recorded the previous year.¹³

40. Moreover, the CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin.¹⁴

41. Heroin is pharmacologically similar to prescription opioids. The majority of current heroin users report having used prescription opioids non-medically before they initiated heroin

¹¹ See Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep’t of Health and Human Servs., Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

¹² See Califf et al., supra note 3.

¹³ See Ctrs. for Disease Control and Prevention, U.S. Dep’t of Health and Human Servs., Provisional Counts of Drug Overdose Deaths, (August 8, 2016), https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-deathestimates.pdf

¹⁴ See Ctrs. for Disease Control and Prevention, U.S. Dep’t of Health and Human Servs., *Today’s Heroin Epidemic*, <https://www.cdc.gov/vitalsigns/heroin/index.html> (last updated July 7, 2015).

use. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use.¹⁵

42. The CDC reports that drug overdose deaths involving heroin continued to climb sharply, with heroin overdoses more than tripling in 4 years. This increase mirrors large increases in heroin use across the country and has been shown to be closely tied to opioid pain reliever misuse and dependence. *Past misuse of prescription opioids is the strongest risk factor for heroin initiation and use*, specifically among persons who report past-year dependence or abuse. The increased availability of heroin, combined with its relatively low price (compared with diverted prescription opioids) and high purity appear to be major drivers of the upward trend in heroin use and overdose.¹⁶

43. The societal costs of prescription drug abuse are “huge.”¹⁷

44. Across the nation, hospitals are struggling with a pernicious, ever-expanding epidemic of opioid addiction and abuse. Every day, more than 90 Americans lose their lives after overdosing on opioids.¹⁸

45. The National Institute on Drug Abuse identifies misuse and addiction to opioids

¹⁵ See Wilson M. Compton, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin*, 374 N. Eng. J. Med. 154 (2016).

¹⁶ See Rose A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014*, 64 Morbidity & Mortality Wkly. Rep. 1378 (2016).

¹⁷ See Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States Dept. Justice*, No. 12-5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *10 [hereinafter Brief of HDMA].

¹⁸ Opioid Crisis, NIH, National Institute on Drug Abuse (available at <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis>, last visited Sept. 19, 2017) (“Opioid Crisis, NIH”) (citing at note 1 Rudd RA, Seth P, David F, Scholl L, Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015, *MMWR MORB MORTAL WKLY REP.* 2016;65, doi:10.15585/mmwr.mm655051e1).

as “a serious national crisis that affects public health as well as social and economic welfare.”¹⁹

The economic burden of prescription opioid misuse alone is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.²⁰

46. The U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999–2014. Among 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.²¹

47. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.²²

48. Every day brings a new revelation regarding the depth of the opioid plague: just to name one example, the New York Times reported in September 2017 that the epidemic, which now claims 60,000 lives a year, is now killing babies and toddlers because ubiquitous, deadly opioids are “everywhere” and mistaken as candy.²³

49. In 2016, the President of the United States declared an opioid and heroin

¹⁹ Opioid Crisis, NIH.

²⁰ *Id.* (citing at note 2 Florence CS, Zhou C, Luo F, Xu L, The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013, *MED CARE* 2016;54(10):901-906, doi:10.1097/MLR.0000000000000625).

²¹ See Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 *Morbidity & Mortality Wkly. Rep.* 1445 (2016).

²² See Volkow & McLellan, *supra* note 1.

²³ Julie Turkewitz, ‘The Pills are Everywhere’: How the Opioid Crisis Claims Its Youngest Victims, N.Y. Times, Sept. 20, 2017 (“It’s a cancer,’ said [grandmother of dead one-year old], of the nation’s opioid problem, ‘with tendrils that are going everywhere.’”).

epidemic.²⁴

50. The epidemic of prescription pain medication and heroin deaths is devastating families and communities across the country.²⁵ Meanwhile, the manufacturers and distributors of prescription opioids extract billions of dollars of revenue from the addicted American public while tens of millions of dollars of injury are caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic.

51. The prescription opioid manufacturers and distributors, including the Defendants, have continued their wrongful, intentional, and unlawful conduct, despite their knowledge that such conduct is causing and/or continuing to the national, state, and local opioid epidemic.

D. THE MANUFACTURER DEFENDANTS' FALSE, DECEPTIVE, AND UNFAIR MARKETING OF OPIOIDS.

52. The opioid epidemic did not happen by accident.

53. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

²⁴ See Proclamation No. 9499, 81 Fed. Reg. 65,173 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Epidemic Awareness Week").

²⁵ See Presidential Memorandum – Addressing Prescription Drug Abuse and Heroin Use, 2015 Daily Comp. Pres. Doc. 743 (Oct. 21, 2015), <https://www.gpo.gov/fdsys/pkg/DCPD-201500743/pdf/DCPD-201500743.pdf>.

54. Each Manufacturer Defendant has conducted, and has continued to conduct, a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain.

55. The Manufacturer Defendants have made false and misleading claims, contrary to the language on their drugs' labels, regarding the risks of using their drugs that: (1) downplayed the serious risk of addiction; (2) created and promoted the concept of "pseudoaddiction" when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools to prevent addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. The Manufacturer Defendants have also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the Manufacturer Defendants' claims.

56. The Manufacturer Defendants have disseminated these common messages to reverse the popular and medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Manufacturer Defendants recruited for their support of their marketing messages, and through unbranded marketing and industry-funded front groups.

57. Defendants' efforts have been wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated \$11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded \$8 billion in revenue annually since 2009.²⁶ In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors ... [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."²⁷ This epidemic has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to buy prescription opioids or even non-prescription opioids, like heroin.

58. The Manufacturer Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

4. Each Manufacturer Defendant Used Multiple Avenues to Disseminate Their False and Deceptive Statements about Opioids.

59. The Manufacturer Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients throughout the United States. Defendants also deployed seemingly unbiased and independent third parties that they controlled

²⁶ See Katherine Eban, *Oxycontin: Purdue Pharma's Painful Medicine*, Fortune, Nov. 9, 2011, <http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/>; David Crow, *Drugmakers Hooked on \$10bn Opioid Habit*, Fin. Times, Aug. 10, 2016, <https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95>.

²⁷ Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016), <http://turnthetiderx.org/>.

to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the State and Plaintiffs' Communities.

60. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that the Manufacturer Defendants' messages are accurately and consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. The Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

61. The Manufacturer Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. The Manufacturer Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

i. Direct Marketing.

62. The Manufacturer Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Manufacturer Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, upon information and belief, the Manufacturer Defendants spent more than \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

63. Many of the Manufacturer Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on

its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker, chef, and teacher, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Upon information and belief, Purdue also ran a series of ads, called “Pain vignettes,” for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a “54-year-old writer with osteoarthritis of the hands” and implied that OxyContin would help the writer work more effectively.

64. Second, each Manufacturer Defendant promoted the use of opioids for chronic pain through “detailers” – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. The Manufacturer Defendants have not corrected this misinformation. Instead, each Defendant devoted massive resources to direct sales contacts with doctors. Upon information and belief, in 2014 alone, the Manufacturer Defendants spent in excess of \$168 million on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000.

65. The Manufacturer Defendants’ detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Even without such studies, the Manufacturer Defendants purchase, manipulate and analyze some of the most sophisticated data available in any industry, data available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by individual doctor, which in turn allows them to target, tailor, and monitor the impact of their core messages. Thus, the Manufacturer Defendants know their detailing to doctors is effective.

66. The Manufacturer Defendants’ detailers have been reprimanded for their deceptive promotions. In March 2010, for example, the FDA found that Actavis had been

distributing promotional materials that “minimize[] the risks associated with Kadian and misleadingly suggest[] that Kadian is safer than has been demonstrated.” Those materials in particular “fail to reveal warnings regarding potentially fatal abuse of opioids, use by individuals other than the patient for whom the drug was prescribed.”²⁸

ii. Indirect Marketing.

67. The Manufacturer Defendants’ indirectly marketed their opioids using unbranded advertising, paid speakers and “key opinion leaders” (“KOLs”), and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as “Front Groups”).

68. The Manufacturer Defendants deceptively marketed opioids throughout the United States through unbranded advertising – e.g., advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, the Manufacturer Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Defendants controlled the distribution of their “core messages” via their own detailers and speaker programs, the Manufacturer Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, Continuing Medical Education (“CME”) programs, and medical conferences and seminars. To this end, the Manufacturer Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

²⁸ Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc’ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), <http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf>.

69. The Manufacturer Defendants marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, the Manufacturer Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long term opioid use for chronic pain.

70. Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

71. Borrowing a page from Big Tobacco's playbook, the Manufacturer Defendants worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors who served as KOLS, and (b) funding, assisting, directing, and encouraging seemingly neutral and credible Front Groups. The Manufacturer Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, CME programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively,

and through these Front Groups and KOLs, the Manufacturer Defendants persuaded doctors and patients that what they have long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and that the compassionate treatment of pain required opioids.

72. In 2007, multiple States sued Purdue for engaging in unfair and deceptive practices in its marketing, promotion, and sale of OxyContin. Certain states settled their claims in a series Consent Judgments that prohibited Purdue from making misrepresentations in the promotion and marketing of OxyContin in the future. By using indirect marketing strategies, however, Purdue intentionally circumvented these restrictions. Such actions include contributing the creation of misleading publications and prescribing guidelines which lack reliable scientific basis and promote prescribing practices which have worsened the opioid crisis.

73. Pro-opioid doctors are one of the most important avenues that the Manufacturer Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. The Manufacturer Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website “In the Face of Pain” failed to disclose that doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue’s failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

74. Defendants utilized many KOLs, including many of the same ones.

75. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom the

Manufacturer Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society (“APS”) / American Academy of Pain Medicine (“AAPM”) Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1996 and again in 2009. He was also a member of the board of the American Pain Foundation (“APF”), an advocacy organization almost entirely funded by the Manufacturer Defendants.

76. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations, such as his claim that “the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low.” He appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast across the country, Dr. Portenoy claimed: “Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted.”²⁹

77. Dr. Portenoy later admitted that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true.” These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to “destigmatize” opioids, he and other doctors promoting them overstated their benefits and

²⁹ Good Morning America (ABC television broadcast Aug. 30, 2010).

glossed over their risks. Dr. Portenoy also conceded that “[d]ata about the effectiveness of opioids does not exist.”³⁰ Portenoy candidly stated: “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did.”³¹

78. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President of American Academy of Pain Medicine (“AAPM”) in 2013. He is a Senior Editor of Pain Medicine, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants (including nearly \$2 million from Cephalon).

79. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice’s Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster’s former patients at the Lifetree Clinic have died of opioid overdoses.

80. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster’s Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue. Unaware of the flawed science and industry bias underlying this

³⁰ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

³¹ *Id.*

tool, certain states and public entities have incorporated the Opioid Risk Tool into their own guidelines, indicating, also, their reliance on the Manufacturer Defendants and those under their influence and control.

81. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue entitled “Managing Patient’s Opioid Use: Balancing the Need and the Risk.” Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent “overuse of prescriptions” and “overdose deaths.” This webinar was available to and was intended to reach doctors throughout the United States.³²

82. Dr. Webster also was a leading proponent of the concept of “pseudoaddiction,” the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster’s description, the only way to differentiate the two was to increase a patient’s dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid Abuse While Managing Pain*—a book that is still available online—when faced with signs of aberrant behavior, increasing the dose “in most cases . . . should be the clinician’s first response.”³³ Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that “[pseudoaddiction] obviously became too much of an excuse to give patients more medication.”³⁴

83. The Manufacturer Defendants also entered into arrangements with seemingly

³² See Emerging Solutions in Pain, *Managing Patient’s Opioid Use: Balancing the Need and the Risk*, http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

³³ Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

³⁴ John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012, <http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html>

unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of the Manufacturer Defendants, these “Front Groups” generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted the Manufacturer Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

84. These Front Groups depended on the Manufacturer Defendants for funding and, in some cases, for survival. The Manufacturer Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, the Manufacturer Defendants made sure that the Front Groups would generate only the messages that the Manufacturer Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

85. Defendants Cephalon, Endo, Janssen, and Purdue, in particular, utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society (“APS”), American Geriatrics Society (“AGS”), the Federation of State Medical Boards (“FSMB”), American Chronic Pain Association (“ACPA”), the Center for Practical Bioethics (“CPB”), the U.S. Pain Foundation (“USPF”) and Pain & Policy Studies Group (“PPSG”).³⁵

³⁵ See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep’t of Health and Human Servs., (May 5, 2015), <https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group.pdf>.

86. The most prominent of the Manufacturer Defendants' Front Groups was the American Pain Foundation ("APF"), which, upon information and belief, received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012, primarily from Endo and Purdue. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers. APF also engaged in a significant multimedia campaign – through radio, television and the internet – to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach citizens of all 50 states.

87. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about \$2.3 million from industry sources out of total income of about \$2.85 million in 2009; its budget for 2010 projected receipts of roughly \$2.9 million from drug companies, out of total income of about \$3.5 million. By 2011, upon information and belief, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit.

88. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. Upon information and belief, it was often called upon to provide "patient representatives" for the Manufacturer Defendants' promotional activities, including for Purdue's Partners Against Pain and Janssen's Let's Talk Pain. APF

functioned largely as an advocate for the interests of the Manufacturer Defendants, not patients. Indeed, upon information and belief, as early as 2001, Purdue told APF that the basis of a grant was Purdue’s desire to “strategically align its investments in nonprofit organizations that share [its] business interests.”

89. Plaintiffs are informed, and believe, that on several occasions, representatives of the Manufacturer Defendants, often at informal meetings at conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

90. The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF’s credibility as an objective and neutral third party, and the Manufacturer Defendants stopped funding it. Within days of being targeted by Senate investigation, APF’s board voted to dissolve the organization “due to irreparable economic circumstances.” APF “cease[d] to exist, effective immediately.”³⁶

91. Another front group for the Manufacturer Defendants was the American Academy of Pain Medicine (“AAPM”). With the assistance, prompting, involvement, and funding of the Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to the Manufacturer Defendants’ deceptive marketing of chronic opioid therapy.

92. AAPM received substantial funding from opioid manufacturers. For example,

³⁶ Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies’ Ties to Pain Groups*, Wash. Post, May 8, 2012, https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html.

AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an “exclusive venue” for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event.

93. Upon information and belief, AAPM is viewed internally by Endo as “industry friendly,” with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM’s presidents have included top industry-supported KOLs Perry Fine and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation.

94. The Manufacturer Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

95. In 1996, AAPM and APS jointly issued a consensus statement, “The Use of Opioids for the Treatment of Chronic Pain,” which endorsed opioids to treat chronic pain and claimed that the risk of a patients’ addiction to opioids was low. Dr. Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM’s website until 2011, and, upon information and belief, was taken down from AAPM’s website only after a doctor

complained.³⁷

96. AAPM and APS issued their own guidelines in 2009 (“AAPM/APS Guidelines”) and continued to recommend the use of opioids to treat chronic pain.³⁸ Treatment guidelines have been relied upon by doctors, especially the general practitioners and family doctors targeted by the Manufacturer Defendants. Treatment guidelines not only directly inform doctors’ prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

97. At least fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue. The 2009 Guidelines promote opioids as “safe and effective” for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.³⁹ One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence

³⁷ *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society*, 13 Clinical J. Pain 6 (1997).

³⁸ Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).

³⁹ *Id.*

on opioids; the Guidelines have been cited hundreds of times in academic literature, were disseminated in the State and/or Plaintiffs' Communities during the relevant time period, are still available online, and were reprinted in the Journal of Pain. The Manufacturer Defendants widely referenced and promoted the 2009 Guidelines without disclosing the lack of evidence to support them or the Manufacturer Defendants financial support to members of the panel.

98. The Manufacturer Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from the Manufacturer Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which the Manufacturer Defendants determined would reduce prescribing.

5. The Manufacturer Defendants' Marketing Scheme Misrepresented the Risks and Benefits of Opioids.

iii. The Manufacturer Defendants embarked upon a campaign of false, deceptive, and unfair assurances grossly understating and misstating the dangerous addiction risks of the opioid drugs.

99. To falsely assure physicians and patients that opioids are safe, the Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low risk because most patients would not become addicted, and

because those at greatest risk for addiction could be identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. The Manufacturer Defendants have not only failed to correct these misrepresentations, they continue to make them today.

100. Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have entered into settlement agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint. Yet even afterward, each Manufacturer Defendant continued to misrepresent the risks and benefits of long-term opioid use and each continues to fail to correct its past misrepresentations.

101. Some illustrative examples of the Manufacturer Defendants' false, deceptive, and unfair claims about the purportedly low risk of addiction include:

- a. Actavis's predecessor caused a patient education brochure, *Managing Chronic Back Pain*, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is "less likely if you have never had an addiction problem." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.⁴⁰
- c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Upon information and belief, another Endo website,

⁴⁰ Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*], <https://assets.documentcloud.org/documents/277605/afp-treatmentoptions.pdf>.

PainAction.com, stated “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.” Endo also distributed an “Informed Consent” document on PainAction.com that misleadingly suggested that only people who “have problems with substance abuse and addiction” are likely to become addicted to opioid medications.

- d. Upon information and belief, Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: “Most health care providers who treat people with pain agree that most people do not develop an addiction problem.”
- e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as “myth” the claim that opioids are addictive, and asserted as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.”
- f. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are “overestimated.”
- g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to “[m]isconceptions about opioid addiction.”⁴¹
- h. Consistent with the Manufacturer Defendants’ published marketing materials, upon information and belief, detailers for Purdue, Endo, Janssen, and Cephalon minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrant formulations; and routinely did not correct the misrepresentations noted above.
- i. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants’ Front Groups APF and NFP argued in an *amicus* brief to the United States Fourth Circuit Court of

⁴¹ Am. Pain Found., *A Policymaker’s Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker’s Guide*],

<http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>.

Appeals that “patients rarely become addicted to prescribed opioids,” citing research by their KOL, Dr. Portenoy.⁴²

102. These claims are contrary to longstanding scientific evidence. A 2016 opioid-prescription guideline issued by the CDC (the “2016 CDC Guideline”) explains that there is “[e]xtensive evidence” of the “possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction], [and] overdose . . .).”⁴³ The 2016 CDC Guideline further explains that “[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder” and that “continuing opioid therapy for 3 months substantially increases risk for opioid use disorder.”⁴⁴

103. The FDA further exposed the falsity of Defendants’ claims about the low risk of addiction when it announced changes to the labels for extended-release and long-acting (“ER/LA”) opioids in 2013 and for immediate release (“IR”) opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘high potential for abuse’” and that opioids “are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death.” According to the FDA, because of the “known serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like

⁴² Brief of the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.

⁴³ Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly. Rep., Mar. 18, 2016, at 15 [hereinafter 2016 CDC Guideline], <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

⁴⁴ *Id.* at 2, 25.

non-opioid drugs have failed.⁴⁵

104. The State of New York, in a 2016 settlement agreement with Endo, found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder.”⁴⁶ Endo had claimed on its www.opana.com website that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted,” but the State of New York found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to “make statements that . . . opioids generally are non-addictive” or “that most patients who take opioids do not become addicted” in New York. Endo remains free, however, to make those statements in this State.

105. In addition to mischaracterizing the highly addictive nature of the drugs they were pushing, the Manufacturer Defendants also fostered a fundamental misunderstanding of the signs of addiction. Specifically, the Manufacturer Defendants misrepresented, to doctors and patients, that warning signs and/or symptoms of addiction were, instead, signs of undertreated pain (i.e. pseudoaddiction) – and instructed doctors to increase the opioid prescription dose for patients

⁴⁵ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep’t of Health and Human Servs., to Andrew Koldny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), <https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf;> Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep’t of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan and Becker, LLP (Mar. 22, 2016), <https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf>.

⁴⁶ Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc.* (Assurance No. 15-228), at 16, https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

who were already in danger.

106. To this end, one of Purdue's employees, Dr. David Haddox, invented a phenomenon called "pseudoaddiction." KOL Dr. Portenoy popularized the term. Examples of the false, misleading, deceptive, and unfair statements regarding pseudoaddiction include:

- a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction.⁴⁷ The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real.⁴⁸
- b. Janssen sponsored, funded, and edited the Let's Talk Pain website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."
- c. Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 entitled "Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia," which, upon information and belief, promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which, upon information and belief, described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug- seeking behaviors] in patients who have pain that has not been effectively treated."
- e. Upon information and belief, Purdue sponsored a CME program titled "Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse". In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting

⁴⁷ Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2007) at 62.

⁴⁸ See Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2d ed. 2012).

opioid.

107. In the 2016 CDC Guideline, the CDC rejects the validity of the pseudoaddiction fallacy invented by a Purdue employee as a reason to push more opioid drugs onto already addicted patients.

108. In addition to misstating the addiction risk and inventing the pseudoaddiction falsehood, a third category of false, deceptive, and unfair practice is the Manufacturer Defendants' false instructions that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because the Manufacturer Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. The Manufacturer Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Illustrative examples include:

- a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.
- b. Purdue, upon information and belief, sponsored a 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."
- c. As recently as 2015, upon information and belief, Purdue has represented in scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

109. The 2016 CDC Guideline confirms the falsity of these claims. The Guideline explains that there are no studies assessing the effectiveness of risk mitigation strategies “for improving outcomes related to overdose, addiction, abuse or misuse.”⁴⁹

110. A fourth category of deceptive messaging regarding dangerous opioids is the Manufacturer Defendants’ false assurances regarding the alleged ease of eliminating opioid dependence. The Manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, but they failed to disclose the increased difficulty of stopping opioids after long-term use. In truth, the 2016 CDC Guideline explains that the symptoms of opioid withdrawal include abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia, drug cravings, anxiety, insomnia, spontaneous abortion and premature labor in pregnant women.⁵⁰

111. The Manufacturer Defendants nonetheless downplayed the severity of opioid detoxification. For example, upon information and belief, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient’s opioid dose by 10%-20% for 10 days. And Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation” without mentioning any hardships that might occur.⁵¹

112. A fifth category of false, deceptive, and unfair statements the Manufacturer Defendants made to sell more drugs is that opioid dosages could be increased indefinitely

⁴⁹ *Id.* at 11.

⁵⁰ *Id.* at 26.

⁵¹ APF, *Policymaker’s Guide*, *supra* note 48, at 32.

without added risk. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. The Manufacturer Defendants' deceptive claims include:

- a. Upon information and belief, Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis appears to have continued to use these materials in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and insinuated that they are therefore the most appropriate treatment for severe pain.⁵² This publication is still available online.
- c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."
- d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."⁵³
- e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.
- f. Upon information and belief, Purdue's In the Face of Pain website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who

⁵² APF, *Treatment Options*, *supra* note 47, at 12.

⁵³ Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).

will.

- g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," and that "the need for higher doses of medication is not necessarily indicative of addiction," but inaccurately downplayed the risks from high opioid dosages.⁵⁴
- h. In 2007, Purdue sponsored a CME entitled "Overview of Management Options" that was available for CME credit and available until at least 2012. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.
- i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders," challenging the correlation between opioid dosage and overdose.⁵⁵
- j. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants' Front Groups APF and NFP argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "there is no 'ceiling dose'" for opioids.⁵⁶

113. Once again, the 2016 CDC Guideline reveals that the Manufacturer Defendants' representations regarding opioids were lacking in scientific evidence. The 2016 CDC Guideline clarifies that the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage."⁵⁷ More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages."⁵⁸ The CDC also states that

⁵⁴ APF, *Policymaker's Guide*, *supra* note 48, at 32.

⁵⁵ The College on Problems of Drug Dependence, *About the College*, <http://cpdd.org> (last visited Aug. 21, 2017).

⁵⁶ Brief of APF, *supra* note 49, at 9.

⁵⁷ 2016 CDC Guideline, *supra* note 50, at 22–23.

⁵⁸ *Id.* at 23–24.

there is an increased risk “for opioid use disorder, respiratory depression, and death at higher dosages.”⁵⁹ That is why the CDC advises doctors to “avoid increasing dosage” to above 90 morphine milligram equivalents per day.⁶⁰

114. Defendants’ deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can cure addiction and abuse.

115. The Manufacturer Defendants made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo’s advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that Opana ER Extended-Release Tablets’ “extended-release features can be compromised, causing the medication to ‘dose dump,’ when subject to . . . forms of manipulation such as cutting, grinding, or chewing, followed by swallowing.”⁶¹ Also troubling, Opana ER can be prepared for snorting using commonly available methods and “readily prepared for injection.”⁶² The letter discussed “the troubling possibility that a higher (and rising) percentage of [Opana ER Extended-Release Tablet] abuse is occurring via injection.”⁶³ Endo’s own studies,

⁵⁹ *Id.* at 21.

⁶⁰ *Id.* at 16.

⁶¹ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep’t of Health and Human Servs., to Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc. (May 10, 2013), at 5.

⁶² *Id.* at 6.

⁶³ *Id.* at 6n.21.

which it failed to disclose, showed that Opana ER could still be ground and chewed. In June 2017, the FDA requested that Opana ER be removed from the market.

iv. The Manufacturer Defendants embarked upon a campaign of false, deceptive, and unfair assurances grossly overstating the benefits of the opioid drugs.

116. To convince doctors and patients that opioids should be used to treat chronic pain, the Manufacturer Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the CDC Guideline makes clear, “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials \leq 6 weeks in duration)” and that other treatments were more or equally beneficial and less harmful than long-term opioid use.⁶⁴ The FDA, too, has recognized the lack of evidence to support long-term opioid use. Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence.

117. Some illustrative examples of the Manufacturer Defendants’ false claims are:

- a. Upon information and belief, Actavis distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve “stress on your body and your mental health,” and help patients enjoy their lives.
- b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
- c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as “a fact” that “opioids may make it easier for people to live normally.” The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.
- d. Janssen promoted Ultracet for everyday chronic pain and distributed posters,

⁶⁴ *Id.* at 15.

for display in doctors' offices, of presumed patients in active professions; the caption read, "Pain doesn't fit into their schedules."

- e. Upon information and belief, Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.
- f. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function.
- g. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve."⁶⁵ This publication is still available online.
- h. Endo's NIPC website "PainKnowledge" claimed in 2009, upon information and belief, that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.
- i. Endo was the sole sponsor, through NIPC, of a series of CMEs entitled "Persistent Pain in the Older Patient."⁶⁶ Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."
- j. Janssen sponsored and funded a multimedia patient education campaign called "Let's Talk Pain." One feature of the campaign was to complain that patients were under-treated. In 2009, upon information and belief, a Janssen-sponsored website, part of the "Let's Talk Pain" campaign, featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function."
- k. Purdue sponsored the development and distribution of APF's *A*

⁶⁵ APF, *Treatment Options*, *supra* note 47.

⁶⁶ E.g., NIPC, *Persistent Pain and the Older Patient* (2007), https://www.painedu.org/Downloads/NIPC/Activities/B173_Providence_RI_%20Invite.pdf.

Policymaker's Guide to Understanding Pain & Its Management, which claimed that “[m]ultiple clinical studies” have shown that opioids are effective in improving “[d]aily function,” “[p]sychological health,” and “[o]verall health-related quality of life for chronic pain.”⁶⁷ The Policymaker’s Guide was originally published in 2011.

1. Purdue’s, Cephalon’s, Endo’s, and Janssen’s sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

118. As the FDA and other agencies have made clear for years, these claims have no support in the scientific literature.

119. In 2010, the FDA warned Actavis, in response to its advertising of Kadian described above, that “we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient’s work, physical and mental functioning, daily activities, or enjoyment of life.”⁶⁸ And in 2008, upon information and belief, the FDA sent a warning letter to an opioid manufacturer, making it clear “that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience.”

120. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing medications like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by

⁶⁷ APF, *Policymaker's Guide*, *supra* note 48, at 29.

⁶⁸ Letter from Thomas Abrams to Doug Boothe, *supra* note 32.

the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort “in patients for which alternative treatment options” like non-opioid drugs “are inadequate.” And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.⁶⁹ Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action. Upon information and belief, Purdue’s own research shows that OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as “end of dose” failure, and the FDA found in 2008 that a “substantial proportion” of chronic pain patients taking OxyContin experience it. This not only renders Purdue’s promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

121. Purdue’s competitors were aware of this problem. For example, upon information and belief, Endo ran advertisements for Opana ER referring to “real” 12-hour

⁶⁹ 2016 CDC Guideline, *supra* note 50, at 12.

dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Upon information and belief, Purdue's sales representatives continue to tell doctors that OxyContin lasts a full 12 hours.

122. Front Groups supported by Purdue likewise echoed these representations. For example, in an amicus brief submitted to the Supreme Court of Ohio by the American Pain Foundation, the National Foundation for the Treatment of Pain and the Ohio Pain Initiative in support of Purdue, those amici represented:

OxyContin is particularly useful for sustained long-term pain because it comes in higher, compact pills with a slow release coating. OxyContin pills can work for 12 hours. This makes it easier for patients to comply with dosing requirements without experiencing a roller-coaster of pain relief followed quickly by pain renewal that can occur with shorter acting medications. It also helps the patient sleep through the night, which is often impossible with short-acting medications. For many of those serviced by Pain Care Amici, OxyContin has been a miracle medication.⁷⁰

123. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007

⁷⁰ Reply Brief of Amicus Curiae of the American Pain Foundation, The National Foundation for the Treatment of Pain and the Ohio Pain Initiative Supporting Appellants, *Howland v. Purdue Pharma L.P.*, No. 2003-1538 (Ohio Apr. 13, 2004), 2004 WL 1637768, at *4 (footnote omitted).

emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.⁷¹ Specifically, the FDA advised that Fentora “is only approved for breakthrough cancer pain in patients who are *opioid-tolerant*, meaning those patients who take a regular, daily, around-the-clock narcotic pain medication.”⁷²

124. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, and for which it is not safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

- a. Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that “[c]linically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility” and recommended Actiq and Fentora for patients with chronic pain.
- b. Upon information and belief, Cephalon’s sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.
- c. In December 2011, Cephalon widely disseminated a journal supplement entitled “Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)” to Anesthesiology News, Clinical Oncology News, and Pain Medicine News – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for “multiple causes of pain” – and not just

⁷¹ See U.S. Food & Drug Admin., *Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets)* (Sept. 26, 2007), <https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm>.

⁷² *Id.*

cancer pain.

125. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

126. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue's sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the Los Angeles Times, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report that a Los Angeles clinic prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described it internally as “an organized drug ring” until years after law enforcement shut it down. In doing so, Purdue protected its own profits at the expense of public health and safety.⁷³

127. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the

⁷³ Harriet Ryan et al., *More Than 1 Million Oxycontin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times, July 10, 2016, <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

6. The Manufacturer Defendants Targeted Susceptible Prescribers and Vulnerable Patient Populations.

128. As a part of their deceptive marketing scheme, the Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the United States. For example, the Manufacturer Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept the Manufacturer Defendants' misrepresentations.

129. The Manufacturer Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. The Manufacturer Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence confirms that elderly patients taking opioids suffer from elevated fall and fracture risks, reduced renal function and medication clearance, and a smaller window between safe and unsafe dosages.⁷⁴ The 2016 CDC Guideline concludes that there must be "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. *Id.* at 27. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

⁷⁴ 2016 CDC Guideline, *supra* note 50, at 13.

7. The Manufacturer Defendants made Materially Deceptive Statements and Concealed Materials Facts.

130. As alleged herein, the Manufacturer Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts, in the course of manufacturing, marketing, and selling prescription opioids. The Manufacturer Defendants' actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

131. Defendant Purdue made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- c. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;
- d. Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- e. Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

- g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic noncancer pain;
- m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- p. Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;

- q. Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to prescribers through in-person detailing; and
- r. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

132. Defendant Endo made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;
- d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;
- e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;
- f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- g. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Providing needed financial support to pro-opioid pain organizations –

including over \$5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- i. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- l. Directly distributing and assisting in the dissemination of literature written by pro- opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and
- n. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing.

133. Defendant Janssen made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that

- opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;
 - d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;
 - e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
 - f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
 - g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
 - h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
 - i. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;
 - j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
 - k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of

pseudoaddiction;

- l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- m. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and
- n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

134. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;
- e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;

- h. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;
- i. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and
- j. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing and speakers' bureau events.

135. Defendant Actavis made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing;
- b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;
- c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

8. The Manufacturer Defendants Fraudulently Concealed Their Misconduct.

136. The Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience establish that opioids are highly addictive and are responsible for a long list of very serious adverse outcomes. The FDA warned Defendants

of this, and Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and death – all of which clearly described the harm from long-term opioid use and that patients were suffering from addiction, overdose, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements, based on medical evidence, that conclusively expose the falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered agreements in New York prohibiting them from making some of the same misrepresentations described in this Complaint.

137. At all times relevant to this Complaint, the Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Manufacturer Defendants disguised their role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Manufacturer Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain. Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. The Manufacturer Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, PainKnowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as Purdue and Janssen, ran similar websites that masked their own role.

138. Finally, the Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these documents were accurate, truthful, and supported by objective evidence when they were not. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented “pseudoaddiction” and promoted it to an unsuspecting medical community. The Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. The Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids’ alleged benefits, disguising the risks, and promoting sales.

E. THE DISTRIBUTOR DEFENDANTS’ UNLAWFUL DISTRIBUTION OF OPIOIDS.

139. The Distributor Defendants owe a duty under federal law (21 U.S.C. § 823, 21 CFR 1301.74) to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted.

140. The foreseeable harm from a breach of these duties is the diversion of prescription opioids for nonmedical purposes.

141. Each Distributor Defendant repeatedly and purposefully breached its duties under state and federal law. Such breaches are a direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes.

142. The unlawful diversion of prescription opioids is a direct and proximate cause of the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality.

143. The Distributor Defendants' intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid epidemic and causing the damages alleged herein.

9. The Distributor Defendants Have a Duty under Federal Law to Guard Against, and Report, Unlawful Diversion and to Report and Prevent Suspicious Orders.

144. Opioids are a controlled substance. These "Schedule II" drugs are controlled substances with a "high potential for abuse." 21 U.S.C. §§ 812(b), 812(2)(A)-(C).

145. Each Distributor Defendant was required to register with the DEA, pursuant to the federal Controlled Substance Act. *See* 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100. Each Distributor Defendant is a "registrant" as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme.

146. Each Distributor Defendant has an affirmative duty under federal law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. §§ 823(b)(1).

147. Federal regulations impose a non-delegable duty upon wholesale drug distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

148. "Suspicious orders" include orders of an unusual size, orders of unusual

frequency or orders deviating substantially from a normal pattern. *See* 21 CFR 1301.74(b). These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

149. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, all flagged orders must be reported. *Id.*

150. These prescription drugs are regulated for the purpose of providing a "closed" system **intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market**, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.⁷⁵

151. Different entities supervise the discrete links in the chain that separate a consumer

⁷⁵ See 1970 U.S.C.C.A.N. 4566, 4571-72.

from a controlled substance. Statutes and regulations define each participant's role and responsibilities.⁷⁶

152. As the DEA advised the Distributor Defendants in a letter to them dated September 27, 2006, wholesale distributors are "one of the key components of the distribution chain. If the closed system is to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as ... the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."⁷⁷

153. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders.⁷⁸

⁷⁶ Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf't Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 [hereinafter Brief for HDMA and NACDS]. The Healthcare Distribution Management Association (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. *See generally* HDA, *About*, <https://www.healthcaredistribution.org/about> (last visited Aug. 21, 2017). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. *See generally* NACDS, *Mission*, <https://www.nacds.org/about/mission/> (last visited Aug. 21, 2017).

⁷⁷ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

⁷⁸ See Brief for HDMA and NACDS, *supra* note 85, 2016 WL 1321983, at *4 ("[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).").

154. The DEA sent a letter to each of the Distributor Defendants on September 27, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, *in addition* to reporting suspicious orders, has a “statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.”⁷⁹ The letter also instructs that “distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.”⁸⁰ The DEA warns that “even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.”

155. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.⁸¹ This letter reminds the Defendants of their statutory and regulatory duties to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.”⁸² The letter further explains:

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., “excessive purchase report” or “high unity purchases”) does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known,

⁷⁹ Rannazzisi Letter, *supra* note 83, at 2

⁸⁰ *Id.* at 1.

⁸¹ *Id.* at 2.

⁸² See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug. Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv- 00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a “normal pattern” to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant’s responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant’s customer base and the patterns throughout the segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating “excessive purchases” do not comply with the requirement to report suspicious orders, even if the registrant calls such reports “suspicious order reports.”

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant’s DEA Certificate of Registration.⁸³

⁸³ *Id.*

Finally, the DEA letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and “some criteria to use when determining whether an order is suspicious.”⁸⁴

156. The Distributor Defendants admit that they “have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”⁸⁵

157. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are “[a]t the center of a sophisticated supply chain” and therefore “are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers.” The guidelines set forth recommended steps in the “due diligence” process, and note in particular: If an order meets or exceeds a distributor’s threshold, as defined in the distributor’s monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.⁸⁶

158. Each of the Distributor Defendants sold prescription opioids, including

⁸⁴ *Id.*

⁸⁵ See Brief of HDMA, *supra* note 19, 2012 WL 1637016, at *2.

⁸⁶ Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App’x B).

hydrocodone and/or oxycodone, to retailers from which Defendants knew prescription opioids were likely to be diverted.

159. Each Distributor Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

160. Each Distributor Defendant owes a duty under federal law to investigate and refuse suspicious orders of prescription opioids.

161. Each Distributor Defendant owes a duty under federal law to report suspicious orders of prescription opioids.

162. Each Distributor Defendant owes a duty under federal law to prevent the diversion of prescription opioids into illicit markets throughout the United States.

163. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction.

164. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality and the damages caused thereby.

10. The Distributor Defendants Breached their Duties.

165. Because distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.⁸⁷

⁸⁷ See Rannazzisi Decl. ¶ 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

166. The sheer volume of prescription opioids distributed to pharmacies in various areas, and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted, was excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.⁸⁸

167. The Distributor Defendants failed to report “suspicious orders,” or which the Distributor Defendants knew were likely to be diverted, to the federal authorities, including the DEA.

168. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern, and/or orders of unusual frequency, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted.

169. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted.

170. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

171. The Distributor Defendants breached their duty to “design and operate a system to disclose to the registrant suspicious orders of controlled substances” and failed to inform the authorities including the DEA of suspicious orders when discovered, in violation of their duties under federal law.

⁸⁸ *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,316, 62,322 (2012)).

172. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.⁸⁹

173. The federal laws at issue here are public safety laws.

174. The Distributor Defendants' violations of public safety statutes constitute prima facie evidence of negligence under State law.

175. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants refuse to abide by the duties imposed by federal law which are required to legally acquire and maintain a license to distribute prescription opiates.

176. The Distributor Defendants acted with actual malice in breaching their duties, *i.e.*, they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

177. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

11. The Distributor Defendants Have Sought to Avoid and Have Misrepresented their Compliance with their Legal Duties.

178. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under federal law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public regarding the Distributor Defendants'

⁸⁹ See *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

compliance with their legal duties.

179. Distributor Defendants have refused to recognize any duty beyond *reporting* suspicious orders. In *Masters Pharmaceuticals*, the HDMA, a trade association run the Distributor Defendants, and the NACDS submitted amicus briefs regarding the legal duty of wholesale distributors. Inaccurately denying the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows:

- a. The Associations complained that the “DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled.”⁹⁰
- b. The Associations argued that, “DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications.”⁹¹
- c. The Associations alleged (inaccurately) that nothing “requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious.”⁹²
- d. The Association complained that the purported “practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties.”⁹³

⁹⁰ Brief for HDMA and NACDS, *supra* note 85, 2016 WL 1321983, at *4–5.

⁹¹ *Id.* at *8 (citations and quotation marks omitted).

⁹² *Id.* at *14.

⁹³ *Id.* at *22.

- e. The Associations alleged (inaccurately) that “DEA’s regulations [] sensibly impose[] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders.”⁹⁴
- f. Also inaccurately, the Associations argued that, “[i]mposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA’s demands.”⁹⁵

180. The positions taken by the trade groups is emblematic of the position taken by the Distributor Defendants in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs.⁹⁶

181. The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. *Masters Pharm., Inc. v. Drug Enf’t Admin.*, 861 F.3d 206 (D.C. Cir. 2017). The D.C. Circuit Court upheld the revocation of Master Pharmaceutical’s license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors must “decline to ship the order, or conduct some ‘due diligence’ and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order.” *Id.* at 212. Master Pharmaceutical was in violation of legal requirements because it failed to conduct necessary investigations and filled suspicious orders. *Id.* at 218–19, 226. A distributor’s investigation must dispel all the red flags giving rise to suspicious circumstance prior to shipping a suspicious order. *Id.* at 226. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above), that, allegedly,

⁹⁴ *Id.* at *24–25

⁹⁵ *Id.* at 26.

⁹⁶ See Brief of HDMA, *supra* note 19, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry “does not know the rules of the road because” they claim (inaccurately) that the “DEA has not adequately explained them”).

the DEA had created or imposed new duties. *Id.* at 220.

182. Wholesale Distributor McKesson has recently been forced to specifically admit to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement (“2017 Agreement”) entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it “did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters.”⁹⁷ Further, the 2017 Agreement specifically finds that McKesson “distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).”⁹⁸ McKesson admitted that, during this time period, it “failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA’s implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers.”

183. The 2017 Memorandum of Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to

⁹⁷ See Administrative Memorandum of Agreement between the U.S. Dep’t of Justice, the Drug Enf’t Admin., and the McKesson Corp. (Jan. 17, 2017), <https://www.justice.gov/opa/press-release/file/928476/download>.

⁹⁸ *Id.* at 4.

the DEA.⁹⁹ In the 2008 Settlement Agreement, McKesson “recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA,” but had failed to do so.¹⁰⁰ The 2017 Memorandum of Agreement documents that McKesson continued to breach its admitted duties by “fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson’s obligations.”¹⁰¹ As a result of these violations, McKesson was fined and required to pay to the United States \$150,000,000.¹⁰²

184. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

185. Because of the Distributor Defendants’ refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant

⁹⁹ *Id.* at 4.

¹⁰⁰ *Id.*

¹⁰¹ *Id.*; see also Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter 2017 Settlement Agreement and Release] (“McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA.”), <https://www.justice.gov/opa/press-release/file/928471/download>.

¹⁰² See 2017 Settlement Agreement and Release, *supra* note 112, at 6.

actions between 2008 and 2012.¹⁰³ The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.¹⁰⁴ These actions include the following:

- a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center (“Orlando Facility”) alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center (“Auburn Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;

¹⁰³ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep’t of Justice, *The Drug Enforcement Administration’s Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

¹⁰⁴ *Id.*

- f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* (“2008 MOA”) with the DEA which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program”;
- g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia (“McDonough Facility”), Valencia, California (“Valencia Facility”) and Denver, Colorado (“Denver Facility”);
- h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of oxycodone;
- i. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and
- j. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a \$150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Sante Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

186. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to “halt” prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a “sharp drop

in enforcement actions” and the passage of the “Ensuring Patient Access and Effective Drug Enforcement Act” which, ironically, raised the burden for the DEA to revoke a distributor’s license from “imminent harm” to “immediate harm” and provided the industry the right to “cure” any violations of law before a suspension order can be issued.¹⁰⁵

187. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

188. For example, a Cardinal Health executive claimed that it uses “advanced analytics” to monitor its supply chain, and represented that it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”¹⁰⁶ Given the sales volumes and the company’s history of violations, this executive was either not telling the truth, or, if Cardinal Health had such a system, it ignored the results.

¹⁰⁵ See Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: “We Had No Leadership” in W Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->.

¹⁰⁶ Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No One Was Doing Their Job,”* Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html.

189. Similarly, Defendant McKesson publicly stated that it has a “best-in-class controlled substance monitoring program to help identify suspicious orders,” and claimed it is “deeply passionate about curbing the opioid epidemic in our country.”¹⁰⁷ Again, given McKesson’s historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

190. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiffs now assert.

191. Meanwhile, the opioid epidemic rages unabated in the United States.

192. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

193. The wrongful actions and omissions of the Distributor Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiffs’ racketeering allegations below.

194. The Distributor Defendants have abandoned their duties imposed under federal law, taken advantage of a lack of DEA law enforcement, and abused the privilege of distributing controlled substances.

¹⁰⁷ Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

F. THE MANUFACTURER DEFENDANTS' UNLAWFUL FAILURE TO PREVENT DIVERSION AND MONITOR, REPORT, AND PREVENT SUSPICIOUS ORDERS.

195. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants were also legally required of the Manufacturer Defendants under federal law.

196. Like the Distributor Defendants, the Manufacturer Defendants were required to register with the DEA to manufacture schedule II controlled substances, like prescription opioids. *See* 21 U.S.C. § 823(a). A requirement of such registration is the:

maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes . .

..

21 USCA § 823(a)(1) (emphasis added).

197. Additionally, as “registrants” under Section 823, the Manufacturer Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 C.F.R. § 1301.74. *See also* 21 C.F.R. § 1301.02 (“Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.”); 21 C.F.R. § 1300.01 (“Registrant means any person who is registered pursuant to either section 303

or section 1008 of the Act (21 U.S.C. 823 or 958).” Like the Distributor Defendants, the Manufacture Defendants breached these duties.

198. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Manufacturer Defendants engaged in the practice of paying “chargebacks” to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer’s product at a price below a specified rate. After a distributor sells a manufacturer’s product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew – just as the Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

199. Federal statutes and regulations are clear: just like opioid distributors, opioid manufacturers are required to “design and operate a system to disclose . . . suspicious orders of controlled substances” and to maintain “effective controls against diversion.” 21 C.F.R. § 1301.74; 21 USCA § 823(a)(1).

200. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.¹⁰⁸

¹⁰⁸ See Press Release, U.S. Dep’t of Justice, Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders>.

201. In the press release accompanying the settlement, the Department of Justice stated: Mallinckrodt did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone Mallinckrodt’s actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . “Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . .”¹⁰⁹

202. Among the allegations resolved by the settlement, the government alleged “Mallinckrodt failed to design and implement an effective system to detect and report ‘suspicious orders’ for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders.”¹¹⁰

203. The Memorandum of Agreement entered into by Mallinckrodt (“2017 Mallinckrodt MOA”) avers “[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA.”¹¹¹

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (July 10, 2017), <https://www.justice.gov/usao-edmi/press-release/file/986026/download>. (“2017 Mallinckrodt MOA”).

204. The 2017 Mallinckrodt MOA further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer:

With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:

- i. conduct adequate due diligence of its customers;
- ii. detect and report to the DEA orders of unusual size and frequency;
- iii. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:
 1. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,
 2. orders that purchased a disproportionate amount of substance which is most often abused compared to other products, and
 3. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallickrodt was aware;
- iv. use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and
- v. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.¹¹²

205. Mallinckrodt agreed that its "system to monitor and detect suspicious orders did

¹¹² 2017 Mallinckrodt MOA at p. 2-3.

not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007.” Mallinckrodt further agreed that it “recognizes the importance of the prevention of diversion of the controlled substances they manufacture” and would “design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers.”¹¹³

206. Mallinckrodt acknowledged that “[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to "downstream" registrants.” Mallinckrodt agreed that, from this data, it would “report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion.”¹¹⁴

207. The same duties imposed by federal law on Mallinckrodt were imposed upon all Distributor Defendants.

208. The same business practices utilized by Mallinckrodt regarding “charge backs” and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including, upon information and belief, the other Distributor Defendants.

209. Through, *inter alia*, the charge back data, the Manufacturer Defendants could

¹¹³ *Id.* at 3-4.

¹¹⁴ *Id.* at p.5.

monitor suspicious orders of opioids.

210. The Manufacturer Defendants failed to monitor, report, and halt suspicious orders of opioids as required by federal law.

211. The Manufacturer Defendants' failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

212. The Manufacturer Defendants have misrepresented their compliance with federal law.

213. The wrongful actions and omissions of the Manufacturer Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiffs' racketeering allegations below.

214. The Manufacturer Defendants' actions and omissions in failing to effective prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids throughout the United States.

G. DEFENDANTS' UNLAWFUL CONDUCT AND BREACHES OF LEGAL DUTIES CAUSED THE HARM ALLEGED HEREIN AND SUBSTANTIAL DAMAGES.

215. As the Manufacturer Defendants' efforts to expand the market for opioids increased so have the rates of prescription and sale of their products — and the rates of opioid-related substance abuse, hospitalization, and death among the people of the United States. The Distributor Defendants have continued to unlawfully ship these massive quantities of opioids.

216. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and

associated adverse outcomes.”¹¹⁵

217. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.¹¹⁶

218. The epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”¹¹⁷

219. The increased abuse of prescription painkillers along with growing sales has contributed to a large number of overdoses and deaths.¹¹⁸

220. As shown above, the opioid epidemic has escalated with devastating effects: substantial opiate-related substance abuse, hospitalization and death that mirrors Defendants’ increased distribution of opioids.

221. Because of the well-established relationship between the use of prescription opioids and the use of non-prescription opioids, like heroin, the massive distribution of opioids by Defendants has caused the Defendant-caused opioid epidemic to include heroin addiction, abuse, and death.

222. Defendants repeatedly and purposefully breached their duties under federal law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes.

223. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction,

¹¹⁵ See Dart et al., *supra* note 11.

¹¹⁶ See Volkow & McLellan, *supra* note 1.

¹¹⁷ See Califf et al., *supra* note 3.

¹¹⁸ See Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep’t of Health and Human Servs., *supra* note 13.

morbidity and mortality in the United States. This diversion and the epidemic are direct causes of foreseeable harms to the Plaintiffs and the members of the proposed Class.

224. Defendants' unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Plaintiffs seek relief, as alleged herein, on behalf of themselves and the members of the proposed Class.

V. FACTS PERTAINING TO THE NAMED PLAINTIFFS AND CLASS MEMBERS

225. Plaintiffs and the Class members have treated, and continue to treat, numerous patients for opioid-related conditions, specifically: (1) opioid overdose; (2) opioid addiction; (3) neonatal treatment for babies born opioid addicted because their mothers were opioid addicts, which treatment is intensive, complex, and lengthy; and (4) psychiatric and related treatment for opioid users who are committed to mental health treatment programs.

226. Additionally, opioid users present themselves to Plaintiffs and the Class members claiming to have illnesses and medical problems, which are actually pretexts for obtaining opioids to satisfy their cravings. Plaintiffs and the Class members incur operational costs, consisting of expending time and incurring expenses, in diagnosing, testing, and otherwise dealing with these "pill seekers" before their true status can be determined and they can be rejected as patients.

227. Plaintiffs and the Class members also incur operational costs in the form of surgical procedures that are more complex and expensive than would otherwise be the case if the patients were not opioid addicts, which complicates surgical procedures and requires special protective measures.

228. Collectively, the patients described above will be referred to herein as "patients with opioid conditions."

229. These patients' opioid conditions are the direct and proximate result of the opioid epidemic created and engineered by Defendants.

230. Plaintiffs and the Class members each have a price list, which sets the prices for a comprehensive listing of items billable to a hospital patient or the patient's health insurance provider.

231. These are the full charges for the hospitals' services. The full charges are only partially reimbursed by private health insurers, Medicare, and Medicaid. Plaintiffs and the Class members have provider agreements with private health insurers whereby they accept payment from the health insurers at a discounted rate on behalf of insured patients. The difference between the full charges and the discounted rate is lost to the hospitals. Medicare and Medicaid bill hospitals at set rates that are less than the hospitals' full charges, and the difference between the set rates and the full charges is lost to the hospitals.

232. Plaintiffs and the Class members bill their full charges to uninsured patients. Typically, where there is no health insurance, Medicare, or Medicaid coverage, these charges are not reimbursed and are lost to hospitals.

233. Plaintiffs and the Class members incur partial monetary losses for patients with health insurance, and total monetary losses for uninsured patients, in the treatment of patients with opioid conditions. These patients would not have presented to Plaintiffs and the Class members, and would not have had opioid conditions, but for the opioid epidemic created and engineered by Defendants. Accordingly, Plaintiffs' and the Class members' aforesaid monetary losses are the direct and proximate result of Defendants' acts and omissions previously specified herein.

234. Because opioids are very dangerous and highly addictive drugs, it was foreseeable to Defendants that the opioid epidemic would result in a corresponding epidemic of

patients with opioid conditions at hospitals. It was also foreseeable to Defendants that Plaintiffs and the Class members would suffer the aforesaid monetary losses because of the opioid epidemic, since hospitals typically are not reimbursed for their treatment of uninsured patients and receive only partial reimbursement for their treatment of patients with health insurance.

VI. CLASS ACTION ALLEGATIONS

235. This action is brought as a plaintiffs' class action pursuant to Federal Rule of Civil Procedure 23(b)(3). Plaintiffs bring this action on their own behalf, and on behalf of all others similarly situated, as representatives of the following Class:

All hospitals in the United States which treated patients with opioid conditions, (1) for four years preceding the commencement of this action with respect to Plaintiffs' RICO claims, and (2) for six years preceding the commencement of this action with respect to Plaintiffs' state-law claims. "Patients with opioid conditions" are defined as patients with opioid overdose; patients with opioid addiction; babies born opioid addicted; opioid users committed to mental health treatment programs; and opioid users with pretextual excuses for obtaining opioids.

Excluded from the Class are any hospitals directly or indirectly owned or operated by Defendants or Defendants' affiliated entities.

236. The members of the Class are readily identifiable from public records.

237. Upon information and belief, the Class consists of thousands of members, and is therefore so numerous that individual joinder of all members is impracticable. The members of the Class are geographically dispersed throughout the United States.

238. There are questions of law and fact common to the Class, which predominate over any questions affecting only individual members of the Class. The wrongs suffered and remedies sought by Plaintiffs and the other members of the Class are premised upon a uniform unlawful scheme perpetuated by Defendants. The sole question affecting only individual members of the Class is the exact monetary recovery to which each Class member is entitled. Plaintiffs'

and the Class members' use of uniform billing codes for patients with opioid conditions will render this determination a simple mechanical one. Questions common to the Class include, but are not limited to, the following:

- a. Did the Manufacturer Defendants use false and deceptive statements and omissions to market opioids?
- b. Did the Manufacturer Defendants market opioids by misrepresenting the risks and benefits of opioids?
- c. Did the Manufacturer Defendants and the Distributor Defendants fail to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids?
- d. Did the Manufacturer Defendants and the Distributor Defendants fail to monitor, detect, investigate, refuse to fill, and report orders of prescription opioids which they knew or should have known were likely to be diverted for nonmedical purposes?
- e. Did the Defendants conduct the affairs of an enterprise through a pattern of racketeering activity?
- f. Did the Defendants conspire to conduct the affairs of an enterprise through a pattern of racketeering activity?
- g. Did the Manufacturer Defendants negligently manufacture, market, and sell opioids?
- h. Did the Distributor Defendants negligently sell and distribute opioids?
- i. Did the Manufacturer Defendants wantonly, recklessly, or with gross negligence manufacture, market, and sell opioids?
- j. Did the Distributor Defendants wantonly, recklessly, or with gross negligence sell and distribute opioids?
- k. Did the Defendants commit common-law fraud by making false representations of material fact and by concealing material facts about opioids?
- l. Were Plaintiffs and the Class members monetarily damaged as a direct and proximate result of the Defendants' acts and omissions?

239. Plaintiffs' claims are typical of those of the Class, and are based on the same legal theories as those of the Class members. Plaintiffs' claims and those of the Class members all arise from the same pattern or practice by the Defendants, set out above.

240. Plaintiffs will fairly and adequately protect the interests of the members of the Class. Plaintiffs have retained counsel who are highly experienced and competent in complex consumer class-action litigation, and Plaintiffs and their counsel intend to prosecute this action vigorously. Neither Plaintiffs nor their counsel have any interests that might cause them not to vigorously pursue this action. Plaintiffs' interests are coextensive with those of the Class, and Plaintiffs have no interests adverse to those of the Class members.

241. Plaintiffs have made arrangements with their counsel for the discharge of their financial responsibilities to the Class. Plaintiffs' counsel has the necessary financial resources to adequately and vigorously litigate this class action.

242. A class action is superior to all other available means for the fair and efficient adjudication of this controversy. It is desirable to concentrate the litigation of the claims in this forum, because the damages suffered by the individual Class members are relatively small compared to the burden and expense that would be entailed by individual litigation of their claims against Defendants. Moreover, the individual Class members are unlikely to be aware of their rights. Thus, it is unlikely that the Class members, on an individual basis, can obtain effective redress for the wrongs done to them. Additionally, the court system would be adversely affected by such individualized litigation. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase delay and expense to all parties and the court system from the issues raised by this action. In contrast, the class-action device provides the benefit of adjudication of these issues in a single

proceeding, with economies of scale and comprehensive supervision by a single court.

243. Plaintiffs and their counsel are aware of no litigation concerning the controversy already begun by or against Class members. This also indicates that the Class members' interest in individually controlling the prosecution of separate actions is minimal.

VII. CAUSES OF ACTION

H. COUNT I

RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT 18 U.S.C. 1961, *et seq.* (Against All Defendants)

244. Plaintiffs reallege and incorporate by reference all preceding paragraphs, and allege as follows on behalf of the themselves and the proposed Class:

245. Plaintiffs bring this Count against the following Defendants, as defined above: Purdue, Cephalon, Janssen, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen (collectively, for purposes of this Count, the "RICO Defendants").

246. The RICO Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise. At all relevant times, the RICO Defendants were "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

247. Section 1962(c) of RICO makes it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." 18 U.S.C. § 1962(c); *United State v. Turkette*, 452 U.S. 576, 580 (1981).

248. The term “enterprise” is defined as including “any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.” 18 U.S.C. § 1961(4); *Turkette*, 452 U.S. at 580; *Boyle v. U.S.*, 556 U.S. 938, 944 (2009). The definition of “enterprise” in Section 1961(4) includes legitimate and illegitimate enterprises within its scope. Specifically, the section “describes two separate categories of associations that come within the purview of an ‘enterprise’ -- the first encompassing organizations such as corporations, partnerships, and other ‘legal entities,’ and the second covering ‘any union or group of individuals associated in fact although not a legal entity.’” *Turkette*, 452 U.S. at 577. The second category is not a more generalized description of the first. *Id.*

249. For over a decade, the RICO Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the RICO Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As “registrants,” the RICO Defendants operated and continue to operate within the “closed-system” created under the Controlled Substances Act, 21 U.S.C. § 821, *et seq.* (the “CSA”). The CSA restricts the RICO Defendants’ ability to manufacture or distribute Schedule II substances like opioids by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

250. The closed-system created by the CSA, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II substances like opioids from “legitimate channels of trade” to the illicit market by controlling the quantities of the basic ingredients needed for the manufacture of [controlled substances].”¹¹⁹

251. Finding it impossible to legally achieve their ever increasing sales ambitions, members of the Opioid Diversion Enterprise (as defined below) systematically and fraudulently violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders.¹²⁰ As discussed in detail below, through the RICO Defendants’ scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA.¹²¹ In doing so, the RICO Defendants allowed hundreds of millions of pills to enter the illicit market which allowed them to generate obscene profits.

252. Defendants’ illegal scheme was hatched by an association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants, and executed in perfect harmony by each of them. In particular, each of the RICO Defendants were associated with, and conducted or participated in, the affairs of the RICO enterprise (defined below and referred to collectively as the “Opioid Diversion Enterprise”), whose purpose was to engage in the unlawful

¹¹⁹ 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

¹²⁰ 21 U.S.C. § 823(a)(1), (b)(1); 21 C.F.R. § 1301.74(b)-(c).

¹²¹ 21 C.F.R. § 1303.11(b); 21 C.F.R. § 1303.23.

sales of opioids, and deceive the public and federal and state regulators into believing that the RICO Defendants were faithfully fulfilling their statutory obligations. The RICO Defendants' scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and/or maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the RICO Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue from the addicted American public, while entities like the Plaintiffs experienced tens of millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic. As explained in detail below, the RICO Defendants' misconduct violated Section 1962(c) and Plaintiffs are entitled to treble damages for their injuries under 18 U.S.C. § 1964(c).

253. Alternatively, the RICO Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically, the Healthcare Distribution Alliance (the "HDA")¹²² is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4) because it is a corporation and a legal entity.

254. On information and belief, each of the RICO Defendants is a member, participant, and/or sponsor of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

¹²² Health Distribution Alliance, [History](#), Health Distribution Alliance, (last accessed on September 15, 2017), <https://www.healthcaredistribution.org/about/hda-history>.

255. Each of the RICO Defendants is a legal entity separate and distinct from the HDA. And, the HDA serves the interests of distributors and manufacturers beyond the RICO Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the RICO Defendants exists separately from the HDA. Therefore, the HDA may serve as a RICO enterprise.

256. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs were each used by the RICO Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs are pleaded in the alternative and are collectively referred to as the “Opioid Diversion Enterprise.”

I. THE OPIOID DIVERSION ENTERPRISE

257. Recognizing that there is a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970.¹²³ The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals.¹²⁴ Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market.¹²⁵ As reflected in comments from United States Senators during deliberation on the CSA, the “[CSA] is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof

¹²³ Joseph T. Rannazzisi Decl. ¶ 4, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12- cv-185 (Document 14-2 February 10, 2012).

¹²⁴ See H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566.

¹²⁵ *Gonzalez v. Raich*, 545 U.S. 1, 12-14 (2005); 21 U.S.C. § 801(20); 21 U.S.C. §§ 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).

balls.”¹²⁶ Congress was concerned with the diversion of drugs out of legitimate channels of distribution when it enacted the CSA and acted to halt the “widespread diversion of [controlled substances] out of legitimate channels into the illegal market.”¹²⁷ Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain.¹²⁸ All registrants -- manufacturers and distributors alike -- must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion.¹²⁹ When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse.¹³⁰ The result is the scourge of addiction that has occurred.

258. In 2006 and 2007, the DEA issued multiple letters to the Distributor Defendants reminding them of their obligation to maintain effective controls against diversion of particular controlled substances, design and operate a system to disclose suspicious orders, and to inform the DEA of any suspicious orders.¹³¹ The DEA also published suggested questions that a

¹²⁶ See H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan 23, 1970).

¹²⁷ See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

¹²⁸ See Statement of Joseph T. Rannazzisi before the Caucus on International Narcotics Control United States Senate, July 18, 2012 (available at <https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/07/18/12/07-18-12-dea-rannazzisi.pdf>).

¹²⁹ *Id.*

¹³⁰ Joseph T. Rannazzisi Decl. ¶ 10, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).

¹³¹ Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (September 27, 2006); Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (December 27, 2007).

distributor should ask prior to shipping controlled substances, in order to “know their customers.”¹³²

259. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from “legitimate channels of trade” by controlling the “quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs.”¹³³ When evaluating production quotas, the DEA was instructed to consider the following information:

- a. Information provided by the Department of Health and Human Services;
- b. Total net disposal of the basic class by all manufacturers;
- c. Trends in the national rate of disposal of the basic class;
- d. An applicant’s production cycle and current inventory position;
- e. Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and
- f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and

¹³² Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf).

¹³³ 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

unforeseen emergencies.¹³⁴

260. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.¹³⁵

261. At all relevant times, the RICO Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by disregarding their statutory duty to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

262. The opioid epidemic has its origins in the mid-1990s when, between 1997 and 2007, per capita purchase of methadone, hydrocodone, and oxycodone increased 13-fold, 4-fold, and 9-fold, respectively. By 2010, enough prescription opioids were sold in the United States to medicate every adult in the country with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.¹³⁶ On information and belief, the Opioid Diversion Enterprise has been ongoing for

¹³⁴ See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United State Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

¹³⁵ *Id.* (citing 21 U.S.C. 842(b)).

¹³⁶ Keyes KM, Cerdá M, Brady JE, Havens JR, Galea S. Understanding the rural-urban differences in nonmedical prescription opioid use and abuse in the United States. Am J Public Health. 2014;104(2):e52-9.

at least the last decade.¹³⁷

263. The Opioid Diversion Enterprise was and is a shockingly successful endeavor. It Opioid Diversion Enterprise has been conducting business uninterrupted since its genesis. But, it was not until recently that United States and State regulators finally began to unravel the extent of the enterprise and the toll that it exacted on the American public.

264. At all relevant times, the Opioid Diversion Enterprise: (a) had an existence separate and distinct from each RICO Defendant; (b) was separate and distinct from the pattern of racketeering in which the RICO Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Defendants; (d) characterized by interpersonal relationships among the RICO Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit.

Turkette, 452 U.S. at 580; *Boyle*, 556 U.S. at 944 (2009). Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the Opioid Diversion Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and then requesting the DEA increase production quotas, all so that the RICO Defendants would have a larger pool of prescription opioids from which to profit.

265. The Opioid Diversion Enterprise also engaged in efforts to lobby against the DEA's authority to hold the RICO Defendants liable for disregarding their duty to prevent

¹³⁷ Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic>.

diversion. Members of the Pain Care Forum (described in greater detail below) and the Healthcare Distribution Alliance lobbied for the passage of legislation to weaken the DEA's enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations¹³⁸ The HDA and other members of the Pain Care Forum contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees and political parties. Plaintiffs are informed and believe that the Pain Care Forum and their members poured at least \$3.5 million into lobbying efforts in this jurisdiction while the HDA devoted over a million dollars a year to its lobbying efforts between 2011 and 2016.

266. The Opioid Diversion Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, the RICO Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity, that involves a fraudulent scheme to increase revenue by violating State and Federal laws requiring the maintenance of effective controls against diversion of prescription opioids, and the identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid

¹³⁸ See HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/>; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->.

sales. But, Defendants' profits were limited by the production quotas set by the DEA, so the Defendants refused to identify, investigate and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

267. The Opioid Diversion Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout the County and this jurisdiction, and the corresponding payment and/or receipt of money from the sale of the same.

268. Within the Opioid Diversion Enterprise, there were interpersonal relationships and common communication by which the RICO Defendants shared information on a regular basis. These interpersonal relationships also formed the organization of the Opioid Diversion Enterprise. The Opioid Diversion Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

269. Each of the RICO Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The RICO Defendants participated in the operation and management of the Opioid Diversion Enterprise by directing its affairs, as described herein. While the RICO Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting

requirements, and financial statements.

270. The RICO Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the Pain Care Forum, the HDA, and through their contractual relationships.

271. The Pain Care Forum (“PCF”) has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

272. The Center for Public Integrity and The Associated Press obtained “internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse.”¹³⁹ Specifically, PCF members spent over \$740 million lobbying in the nation’s capital and in all 50 statehouses on an array of issues, including opioid-related measures.¹⁴⁰

273. Not surprisingly, each of the RICO Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.¹⁴¹ In 2012, membership and participating organizations included the HDA (of which all RICO

¹³⁹ Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic> (emphasis added).

¹⁴⁰ *Id.*

¹⁴¹ PAIN CARE FORUM 2012 Meetings Schedule, (last updated December 2011), <https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf>

Defendants are members), Endo, Purdue, Johnson & Johnson (the parent company for Janssen Pharmaceuticals), Actavis (*i.e.*, Allergan), and Teva (the parent company of Cephalon).¹⁴² Each of the Manufacturer Defendants worked together through the PCF to advance the interests of the enterprise. But, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.¹⁴³ Plaintiffs are informed and believe that the Distributor Defendants participated directly in the PCF as well.

274. The 2012 Meeting Schedule for the Pain Care Forum is particularly revealing on the subject of the Defendants' interpersonal relationships. The meeting schedule indicates that meetings were held in the D.C. office of Powers Pyles Sutter & Verville on a monthly basis, unless otherwise noted. Local members were "encouraged to attend in person" at the monthly meetings. And, the meeting schedule indicates that the quarterly and year-end meetings included a "Guest Speaker."

275. The 2012 Pain Care Forum Meeting Schedule demonstrates that each of the Defendants participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drug makers and their allies whose sole purpose was to shape the national response to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the PCF undertook on behalf of its members.

¹⁴² *Id.* Plaintiff is informed and believes that Mallinckrodt became an active member of the PCF sometime after 2012.

¹⁴³ *Id.* The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. Executive Committee, Healthcare Distribution Alliance (accessed on September 14, 2017), <https://www.healthcaredistribution.org/about/executive-committee>.

276. Second, the HDA -- or Healthcare Distribution Alliance -- led to the formation of interpersonal relationships and an organization between the RICO Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants named in the Complaint, including Actavis (*i.e.*, Allergan), Endo, Purdue, Mallinckrodt and Cephalon were members of the HDA.¹⁴⁴ And, the HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

277. In fact, the HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, “network one on one with manufacturer executives at HDA’s members-only Business and Leadership Conference,” “networking with HDA wholesale distributor members,” “opportunities to host and sponsor HDA Board of Directors events,” “participate on HDA committees, task forces and working groups with peers and trading partners,” and “make connections.”¹⁴⁵ Clearly, the HAD and the Distributor Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturers and Defendants.

278. The application for manufacturer membership in the HDA further indicates

¹⁴⁴ Manufacturer Membership, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/about/membership/manufacturer>.

¹⁴⁵ Manufacturer Membership Benefits, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en>.

the level of connection that existed between the RICO Defendants.¹⁴⁶ The manufacturer membership application must be signed by a “senior company executive,” and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its most recent year end net sales through any HDA distributors, including but not limited to, Defendants AmerisourceBergen, Cardinal Health, and McKesson.¹⁴⁷

279. After becoming members, the Distributors and Manufacturers were eligible to participate on councils, committees, task forces and working groups, including:

- a. Industry Relations Council: “This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues.”¹⁴⁸
- b. Business Technology Committee: “This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee’s major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce.” Participation in this committee includes distributors and manufacturer members.¹⁴⁹
- c. Health, Beauty and Wellness Committee: “This committee conducts research, as well as creates and exchanges industry knowledge to help shape the future of the distribution for health, beauty and wellness/consumer products in the healthcare supply chain.” Participation in this committee includes distributors and manufacturer members.¹⁵⁰

¹⁴⁶ Manufacturer Membership Application, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturer-membership-application.ashx?la=en>.

¹⁴⁷ *Id.*

¹⁴⁸ Councils and Committees, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/about/councils-and-committees>.

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

- d. Logistics Operation Committee: “This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement.” Participation in this committee includes distributors and manufacturer members.¹⁵¹
- e. Manufacturer Government Affairs Advisory Committee: “This committee provides a forum for briefing HDA’s manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement.” Participation in this committee includes manufacturer members.¹⁵²
- f. Bar Code Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.¹⁵³
- g. eCommerce Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.¹⁵⁴
- h. ASN Working Group: Participation includes Distributor, Manufacturer and Service Provider Members.¹⁵⁵

280. Contracts and Chargebacks Working Group: “This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

and chargeback professionals.” Participation includes Distributor and Manufacturer Members.¹⁵⁶

281. The councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the enterprise’s organization.

282. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA, and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to “bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues.”¹⁵⁷ The conferences also gave the Manufacturer and Distributor Defendants “unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry.”¹⁵⁸ The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high-level of leadership. And, it is clear that the Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.¹⁵⁹

283. Third, the RICO Defendants maintained their interpersonal relationships by working together and exchanging information and driving the unlawful sales of their opioids

¹⁵⁶ *Id.*

¹⁵⁷ Business and Leadership Conference – Information for Manufacturers, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers>.

¹⁵⁸ *Id.*

¹⁵⁹ 2015 Distribution Management Conference and Expo, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/events/2015-distribution-management-conference>.

through their contractual relationships, including chargebacks and vault security programs.

284. The Manufacturer Defendants engaged in an industry-wide practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids.¹⁶⁰ As reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the HDA, there is an industry-wide practice whereby the Manufacturers paid the Distributors rebates and/or chargebacks on their prescription opioid sales.¹⁶¹ On information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.¹⁶² The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

285. The contractual relationships among the RICO Defendants also include vault security programs. The RICO Defendants are required to maintain certain security protocols

¹⁶⁰ Lenny Bernstein & Scott Higham, The government's struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356; see also, Letter from Sen. Claire McCaskill, (July 27, 2017), <https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png>; Letter from Sen. Claire McCaskill, (July 27, 2017), <https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png>; Letters From Sen. Claire McCaskill, (March 28, 2017), <https://www.mccaskill.senate.gov/opioid-investigation>; Purdue Managed Markets, Purdue Pharma, (accessed on September 14, 2017), <http://www.purduepharma.com/payers/managed-markets/>.

¹⁶¹ *Id.*

¹⁶² Webinars, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/resources/webinar-leveraging-edi>.

and storage facilities for the manufacture and distribution of their opiates. Plaintiffs are informed and believe that manufacturers negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. Plaintiffs are informed and believe that these agreements were used by the RICO Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

286. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The RICO Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the Pain Care Forum are but two examples of the overlapping relationships, and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the RICO Defendants was in communication and cooperation.

287. According to articles published by the Center for Public Integrity and The Associated Press, the Pain Care Forum -- whose members include the Manufacturers and the Distributors' trade association has been lobbying on behalf of the Manufacturers and Distributors for "more than a decade."¹⁶³ And, from 2006 to 2016 the Distributors and Manufacturers worked together through the Pain Care Forum to spend over \$740 million lobbying in the nation's capital

¹⁶³ Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic>.

and in all 50 statehouses on issues including opioid-related measures.¹⁶⁴ Similarly, the HDA has continued its work on behalf of Distributors and Manufacturers, without interruption, since at least 2000, if not longer.¹⁶⁵

288. As described above, the RICO Defendants began working together as early as 2006 through the Pain Care Forum and/or the HDA to promote the common purpose of their enterprise. Plaintiffs are informed and believe that the RICO Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

J. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE

289. During the time period alleged in this Complaint, the RICO Defendants exerted control over, conducted and/or participated in the Opioid Diversion Enterprise by fraudulently failing to comply with their Federal and State obligations to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, to halt such unlawful sales and, in doing so, to increase production quotas and generate unlawful profits, as follows:

290. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

291. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids.

292. Defendants disseminated false and misleading statements to the public

¹⁶⁴ *Id.*

¹⁶⁵ HDA History, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/about/hda-history>.

claiming that they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.

293. Defendants paid nearly \$800 million dollars to influence local, state and federal governments through joint lobbying efforts as part of the Pain Care Forum. The RICO Defendants were all members of their Pain Care Forum either directly or indirectly through the HDA. The lobbying efforts of the Pain Care Forum and its members, included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids.

294. The RICO Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

295. The RICO Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."¹⁶⁶

296. The RICO Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. Plaintiffs are informed and

¹⁶⁶ See HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/>; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->.

believe that the Manufacturer Defendants used the chargeback program to acquire detailed high-level data regarding sales of the opioids they manufactured. And, Plaintiffs are informed and believe that the Manufacturer Defendants used this high-level information to direct the Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

297. The Manufacturer Defendants lobbied the DEA to increase Aggregate Production Quotas, year after year by submitting net disposal information that the Manufacturer Defendants knew included sales that were suspicious and involved the diversion of opioids that had not been properly investigated or reported by the RICO Defendants.

298. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the RICO Defendants identify suspicious orders or customers who were likely to divert prescription opioids.¹⁶⁷ On information and belief, the "know your customer" questionnaires informed the RICO Defendants of the number of pills that the pharmacies sold, how many non-controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

299. The RICO Defendants refused to identify, investigate and report suspicious

¹⁶⁷ Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq. Pharmaceutical Production Diversion: Beyond the PDMA, Purdue Pharma and McQuite Woods LLC, (available at https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. The RICO Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012¹⁶⁸ and 117 recommended decision in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders -- all for failure to report suspicious orders.¹⁶⁹

300. Defendants' scheme had decision-making structure that was driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants worked together to control the State and Federal Government's response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and identify suspicious orders and report them to the DEA.

301. The RICO Defendants worked together to control the flow of information and influence state and federal governments and political candidates to pass legislation that was pro- opioid. The Manufacturer and Distributor Defendants did this through their participation in the Pain Care Forum and Healthcare Distributors Alliance.

302. The RICO Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious orders or diversion of prescription opioids, the RICO Defendants ensured that the DEA had no

¹⁶⁸ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

¹⁶⁹ *Id.*

basis for refusing to increase or decrease the production quotas for prescription opioids due to diversion of suspicious orders. The RICO Defendants influenced the DEA production quotas in the following ways:

- a. The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the Pain Care Forum;
- b. The Distributor Defendants invited the participation, oversight and control of the Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;
- c. The Distributor Defendants provided sales information to the Manufacturer Defendants regarding their prescription opioids, including reports of all opioids prescriptions filled by the Distributor Defendants;
- d. The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;
- e. The Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing opioids."¹⁷⁰
- f. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;
- g. The Manufacturer Defendants used the Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;
- h. The RICO Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;

¹⁷⁰ Harriet Ryan, et al., More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew, Los Angeles Times, (July 10, 2016), <http://www.latimes.com/projects/la-me-oxycontin-part2/>

- i. The RICO Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders; and
- j. The RICO Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the “medical need” for and the net disposal of their drugs did not justify the production quotas set by the DEA.

303. The scheme devised and implemented by the RICO Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

K. PATTERN OF RACKETEERING ACTIVITY.

304. The Rico Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343); and 18 § 1961(D) by the felonious manufacture, importation, receiving, concealment buying selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

12. The RICO Defendants Engaged in Mail and Wire Fraud.

305. The RICO Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public by knowingly conducting or participating in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

306. The RICO Defendants committed, conspired to commit, and/or aided and

abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by the RICO Defendants’ regular use of the facilities, services, distribution channels, and employees of the Opioid Diversion Enterprise. The RICO Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

307. The RICO Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

308. In devising and executing the illegal scheme, the RICO Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, the RICO Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

309. The RICO Defendants’ predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

- a. Mail Fraud: The RICO Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent

and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

- b. Wire Fraud: The RICO Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, and misrepresentations, promises, and omissions.

310. The RICO Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturers, Distributors, or third parties that were foreseeably caused to be sent as a result of the RICO Defendants' illegal scheme, including but not limited to:

- a. The prescription opioids themselves;
- b. Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;
- c. Defendants' DEA registrations;
- d. Documents and communications that supported and/or facilitated Defendants' DEA registrations;
- e. Documents and communications that supported and/or facilitated the Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;
- f. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;
- g. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- h. Documents intended to facilitate the manufacture and

- distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;
- i. Documents for processing and receiving payment for prescription opioids;
 - j. Payments from the Distributors to the Manufacturers;
 - k. Rebates and chargebacks from the Manufacturers to the Distributors;
 - l. Payments to Defendants' lobbyists through the Pain Care Forum;
 - m. Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;
 - n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and
 - o. Other documents and things, including electronic communications.

311. On information and belief, the RICO Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

312. Purdue manufactures multiple forms of prescription opioids, including but not limited to: OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER. Purdue manufactured and shipped these prescription opioids to the Distributor Defendants.

313. The Distributor Defendants shipped Purdue's prescription opioids throughout the United States.

314. Cephalon manufactures multiple forms of prescription opioids, including but

not limited to: Actiq and Fentora. Cephalon manufactured and shipped these prescription opioids to the Distributor Defendants.

315. The Distributor Defendants shipped Teva's prescription opioids throughout the United States.

316. Janssen manufactures prescription opioids known as Duragesic. Janssen manufactured and shipped its prescription opioids to the Distributor Defendants.

317. The Distributor Defendants shipped Janssen's prescription opioids throughout the United States.

318. Endo manufactures multiple forms of prescription opioids, including but not limited to: Opana/Opana ER, Percodan, Percocet, and Zydome. Endo manufactured and shipped its prescription opioids to the Distributor Defendants.

319. The Distributor Defendants shipped Janssen's prescription opioids throughout the United States.

320. Actavis manufactures multiple forms of prescription opioids, including but not limited to: Kadin and Norco, as well as generic versions of the drugs known as Kadian, Duragesic and Opana. Actavis manufactured and shipped its prescription opioids to the Distributor Defendants.

321. The Distributor Defendants shipped Actavis' prescription opioids throughout the United States.

322. Mallinckrodt manufactures multiple forms of prescription opioids, including but not limited to: Exalgo and Roxicodone.

323. The Distributor Defendants shipped Mallinckrodt's prescription opioids throughout the United States.

324. The RICO Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

325. At the same time, the RICO Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids and that they complied with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

326. Plaintiffs are also informed and believe that the RICO Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

327. The RICO Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

328. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Defendants' scheme and common course of conduct was intended to increase or maintain high production quotas for their prescription opioids from which they could profit.

329. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate

wire facilities have been deliberately hidden, and cannot be alleged without access to Defendants' books and records. But, Plaintiffs have described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

330. The RICO Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. § 1962(c). Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the RICO Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the RICO Defendants.

331. The RICO Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

332. The RICO Defendants hid from the general public, and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities, about the reality of the suspicious orders that the RICO Defendants were filling on a daily basis -- leading to the diversion of a tens of millions of doses of prescription opioids into the illicit market.

333. The RICO Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

334. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids

and refusing to report suspicious orders.

335. As described herein, the RICO Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

336. The predicate acts all had the purpose of generating significant revenue and profits for the RICO Defendants while Plaintiffs were left with substantial monetary losses through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the RICO Defendants through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme.

337. The pattern of racketeering activity alleged herein and the Opioid Diversion Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the enterprise.

338. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future.

339. Many of the precise dates of the RICO Defendants' criminal actions at issue here have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioids Addiction and Opioid Diversion Enterprise alleged herein depended upon secrecy.

340. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar

results affecting similar victims, including the Plaintiffs and the proposed Class members. Defendants calculated and intentionally crafted the Opioid Diversion Enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such behavior would have on consumers, Plaintiffs, or the proposed Class members. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding Defendants' products and their manufacture and distribution of those products.

341. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

342. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Plaintiffs as set out herein, by allowing the flow of prescription opioids from appropriate medical channels into the illicit drug market.

343. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

v. *The RICO Defendants Manufactured, Sold and/or Dealt in Controlled Substances and Their Crimes Are Punishable as Felonies.*

344. The RICO Defendants conducted and participated in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

345. The RICO Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of section 483(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 483(d)(1).

346. Each of the RICO Defendants qualify as registrants under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances., and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

347. Pursuant to the CSA and the Code of Federal Regulations, the RICO Defendants were required to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

348. The RICO Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA including the Manufacturer Defendants' applications for production quotas. Specifically, the RICO Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

349. For example, The DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23,

2015, McKesson filed a Form-8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay \$150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.¹⁷¹

350. Purdue's experience in Los Angeles is another striking example of Defendants' willful violation of the CSA and Code of Federal Regulations as it relates to reporting suspicious orders of prescription opioids. In 2016, the Los Angeles Times reported that Purdue was aware of a pill mill operating out of Los Angeles yet failed to alert the DEA.¹⁷² The LA Times uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. A Purdue sales manager spoke with company officials in 2009 about the prescriber, asking "Shouldn't the DEA be contacted about this?" and adding that she felt "very certain this is an organized drug ring."¹⁷³ Despite knowledge of the staggering amount of pills being issued in Los Angeles, and internal discussion of the problem, "Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals."¹⁷⁴

¹⁷¹ McKesson, [McKesson Finalizes Settlement with U.S. Department of Justice and U.S. Drug Enforcement Administration to Resolve Past Claims](#), About McKesson / Newsroom / Press Releases, (January 17, 2017()), <http://www.mckesson.com/about-mckesson/newsroom/press-releases/2017/mckesson-finalizes-settlement-with-doj-and-dea-to-resolve-past-claims/>.

¹⁷² Harriet Ryan, et al., [More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew](#), Los Angeles Times, (July 10, 2016), <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

¹⁷³ *Id.*

¹⁷⁴ *Id.*

351. Finally, Mallinckrodt was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012.¹⁷⁵ After six years of DEA investigation, Mallinckrodt agreed to a settlement involving a \$35 million fine. Federal prosecutors summarized the case by saying that Mallinckrodt's response was that everyone knew what was going on in Florida but they had no duty to report it.¹⁷⁶

352. Plaintiffs are informed and believe that the foregoing examples reflect the RICO Defendants' pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74. This conclusion is supported by the sheer volume of enforcement actions available in the public record against the Distributor Defendants.¹⁷⁷ For example:

353. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

354. On November 28, 2007, the DEA issued an *Order to Show Cause and*

¹⁷⁵ Lenny Bernstein & Scott Higham, The government's struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356. This number accounted for 66% of all oxycodone sold in the state of Florida during that time.

¹⁷⁶ *Id.*

¹⁷⁷ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center (“Auburn Facility”) for failure to maintain effective controls against diversion of hydrocodone;

355. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of hydrocodone;

356. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone;

357. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;

358. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* (“2008 MOA”) with the DEA which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program”;

359. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia

(“McDonough Facility”), Valencia, California (“Valencia Facility”) and Denver, Colorado (“Denver Facility”);

360. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of oxycodone;

361. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

362. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a \$150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

363. These actions against the Distributor Defendants confirm that the Distributors knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate, on information and belief, that the Manufacturer Defendants were aware of the enforcement against their Distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

364. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future.

365. Many of the precise dates of Defendants’ criminal actions at issue herein

were hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise depended upon the secrecy of the participants in that enterprise.

366. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers and Plaintiffs and the proposed Class members. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on consumers, Plaintiffs, and the proposed Class members.

367. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

368. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations would harm Plaintiffs as set out herein by allowing the flow of prescription opioids from appropriate medical channels into the illicit drug market.

369. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

L. DAMAGES

370. The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiffs and the proposed Class members injury in their businesses, as described above in language expressly incorporated herein by reference.

371. Plaintiffs' and the proposed Class members' injuries were proximately caused

by Defendants' racketeering activities. But for the RICO Defendants' conduct, Plaintiffs and the proposed Class members would not have incurred the monetary losses described above and expressly incorporated herein by reference.

372. Plaintiffs' and the proposed Class members' injuries were directly caused by the RICO Defendants' racketeering activities.

373. Plaintiffs seek actual damages, treble damages, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

COUNT II

RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT 18 U.S.C. 1962(d), *et seq.* (Against All Defendants)

374. Plaintiffs reallege and incorporate by reference all preceding paragraphs, and allege as follows on behalf of themselves and the proposed Class.

375. Plaintiffs' and the proposed Class members' injuries were proximately caused by Defendants' racketeering activities. But for the RICO Defendants' conduct, Plaintiffs and the proposed Class members would not have incurred the monetary losses described above and expressly incorporated herein by reference.

376. Defendants conspired to violate Section 1962(c), as alleged more fully above, by conducting the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity, as incorporated by reference below.

THE OPIOID DIVERSION ENTERPRISE.

377. For efficiency and avoiding repetition, for purposes of this claim, Plaintiffs incorporate by reference Paragraphs 257 through 288 concerning the Opioid Diversion Enterprise.

CONDUCT OF THE OPIOID DIVERSION ENTERPRISE.

378. For efficiency and avoiding repetition, for purposes of this claim, Plaintiffs incorporate by reference Paragraphs 289 through 303 concerning the Opioid Diversion Enterprise.

PATTERN OF RACKETEERING ACTIVITY.

379. For efficiency and avoiding repetition, for purposes of this claim, Plaintiffs incorporate by reference Paragraphs 304 through 369 concerning the Opioid Diversion Enterprise.

DAMAGES

380. The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiffs' and the proposed Class members injury in their businesses, as described above in language expressly incorporated herein by reference.

381. Plaintiffs bring this claim against all RICO Defendants. At all relevant times, the RICO Defendants were associated with the Opioid Diversion Enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(d). Under Section 1962(d) it is unlawful for "any person to conspire to violate" Section 1962(c), among other provisions. 18 U.S.C. § 1962(d).

382. Plaintiffs' and the proposed Class members' injuries were directly caused by the RICO Defendants' racketeering activities.

383. Plaintiffs seek actual damages, treble damages, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

COUNT III

NEGLIGENCE (Against All Defendants)

384. Plaintiffs reallege and incorporate by reference paragraphs 1 through 243 hereof, and allege as follows on behalf of themselves and the proposed Class.

385. Under State law, to establish actionable negligence, one must show in addition to the existence of a duty, a breach of that duty, and injury resulting proximately therefrom. All such essential elements exist here.

386. Each Defendant had duties to exercise reasonable, or due, care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs.

387. Each Defendant breached its aforesaid duties by its conduct previously specified herein.

388. Each Defendant owed its aforesaid duties to the Plaintiffs and the members of the proposed Class because the injuries alleged herein were foreseeable by the Defendants.

389. Plaintiffs and the members of the proposed Class seek compensatory damages for their monetary losses previously specified herein, plus interest and the costs of this action.

COUNT IV

WANTONNESS, RECKLESSNESS, AND GROSS NEGLIGENCE (Against All Defendants)

390. Plaintiffs reallege and incorporate by reference paragraphs 1 through 243 hereof, and allege as follows on behalf of themselves and the proposed Class:

391. Defendants' aforesaid acts and omissions were done and omitted knowing that injury to Plaintiffs and the Class members would likely or probably result; were done or omitted with a reckless or conscious disregard of the rights of Plaintiffs and the Class members; were done

or omitted without the exercise of even a slight degree of care; were done or omitted with conscious indifference to the consequences; and/or constituted a substantial deviation from the standard of care applicable.

392. As a direct and proximate result of Defendants' wantonness, recklessness, or gross negligence, Plaintiffs and the Class members were monetarily damaged as aforesaid. Plaintiffs seek compensatory and punitive damages, plus the costs of this action.

COUNT V

COMMON LAW FRAUD (Against All Defendants)

393. Plaintiffs reallege and incorporate by reference paragraphs 1 through 243 hereof, and allege as follows on behalf of themselves and the proposed Class.

394. As alleged herein, Defendants made false representations and concealed material facts about opioids.

395. Defendants made misrepresentations and failed to disclose material facts to physicians and consumers throughout the United States, to induce the physicians to prescribe and administer, and consumers to purchase and consume, opioids as set forth herein.

396. Defendants' false representations and omissions were material, and were made and omitted intentionally or recklessly.

397. Defendants intended that physicians and consumers would rely upon their misrepresentations and omissions.

398. Physicians and consumers reasonably relied on Defendants' misrepresentations and omissions. Physicians prescribed and administered, and consumers purchased and consumed, opioids as set forth herein.

399. Because of physicians' and consumers' reliance on Defendants'

misrepresentations and omissions of material fact, Plaintiffs and the Class members have suffered monetary damages as aforesaid. Plaintiffs seek compensatory and punitive damages, plus the costs of this action.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs on behalf of themselves and all others similarly situated, ask that the Court:

- (a) Certify the Class proposed herein;
- (b) Appoint Plaintiffs as representatives of the Class;
- (c) Appoint Plaintiffs' counsel as attorneys for the Class;
- (d) Enter judgment awarding Plaintiffs and the Class members monetary damages, compensatory in nature, on their negligence claim;
- (e) Enter judgment awarding Plaintiffs and the Class members monetary damages, compensatory and punitive, on their claims for wanton, reckless, and grossly negligent conduct, and on their claims for fraud;
- (f) Enter judgment awarding Plaintiffs and the Class members treble damages on their RICO claims;
- (g) Award Plaintiffs and the class members prejudgment interest and post-judgment interest as provided by law;
- (h) Award Plaintiffs and the Class members a reasonable attorney's fee and costs; and
- (i) Provide such further relief as may be just and proper.

JURY DEMAND

Plaintiffs, on behalf of themselves and the Class members, demand a trial by jury on all issues so triable.

Respectfully Submitted,

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Exhibit 15

Southwest Miss. Reg'l Med. Ctr., et al. v. AmerisourceBergen Drug Corp., et al,
No. 1:17-op-45175 [Dkt. No. 31] (N.D. Ohio, Mar. 11, 2019)

**THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION

ST. VINCENT MEDICAL CENTER,
SOUTHWEST MISSISSIPPI REGIONAL
MEDICAL CENTER; INFIRMARY
HEALTH HOSPITALS, INC.; and
MONROE COUNTY HEALTHCARE
AUTHORITY, d/b/a MONROE COUNTY
HOSPITAL; on behalf of themselves and
all others similarly situated,

Plaintiffs,

v.

AMERISOURCEBERGEN DRUG
CORPORATION; CARDINAL HEALTH,
INC.; MCKESSON CORPORATION;
PURDUE PHARMA L.P.; PURDUE
PHARMA, INC.; THE PURDUE
FREDERICK COMPANY, INC.;
RICHARD SACKLER; BEVERLY
SACKLER; DAVID SACKLER; ILENE
SACKLER LEFCOURT; JONATHAN
SACKLER; KATHE SACKLER; JOHN
STEWART; MARK TIMNEY; CRAIG
LANDAU; RUSSELL GASDIA;
MORTIMER D.A. SACKLER; THERESA
SACKLER; TEVA PHARMACEUTICAL
INDUSTRIES, LTD.; TEVA
PHARMACEUTICALS USA, INC.;
CEPHALON, INC.; JOHNSON &
JOHNSON; JANSSEN
PHARMACEUTICALS, INC.; SPECGX
LLC; ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC. n/k/a
JANSSEN PHARMACEUTICA, INC.;
NORAMCO, INC.; ENDO HEALTH
SOLUTIONS INC.; ENDO

MDL No. 2804

Case No. 1:17-MD-2804

Hon. Dan A. Polster

**FIRST AMENDED
CLASS ACTION COMPLAINT**

JURY TRIAL DEMANDED

PHARMACEUTICALS, INC.; MIAMI-LUKEN, INC.; INSYS THERAPEUTICS, INC., ALLERGAN PLC f/k/a ACTAVIS PLC; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; MALLINCKRODT PLC; MALLINCKRODT LLC; CVS HEALTH CORPORATION; THE KROGER CO.; RITE-AID OF MARYLAND, INC.; ABBOTT LABORATORIES; ABBOTT LABORATORIES, INC.; AMNEAL PHARMACEUTICALS, LLC; ANDA, INC.; H.D. SMITH, LLC f/k/a H.D. SMITH WHOLESALE DRUG CO.; HENRY SCHEIN, INC.; DEPOMED, INC.; WALGREENS BOOTS ALLIANCE, INC.; WAL-MART, INC.; and DOES 1-100,

Defendants.

This document relates to:

Case No. 1:17-op-45175-DAP

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JURY DEMAND 335

The decade of the 1990s was the era of the blockbuster drug, the billion-dollar pill, and a pharmaceutical sales force arms race was part of the excess of the time ... A pharmaceutical Wild West emerged. Salespeople stampeded into offices. They made claims that helped sell the drugs to besieged doctors. Those claims also lead years later to blockbuster lawsuits and criminal cases against their companies.¹

COMPLAINT

Plaintiffs St. Vincent Charity Medical Center (“St. Vincent”) (at times d/b/a Rosary Hall), Southwest Mississippi Regional Medical Center, Infirmary Health Hospitals, Inc., and Monroe County Healthcare Authority, d/b/a Monroe County Hospital bring (collectively, “Plaintiffs”) bring this Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Noramco, Inc.; Amneal Pharmaceuticals, LLC; Teva Pharmaceutical Industries, Ltd; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Abbott Laboratories; Abbott Laboratories, Inc.; Depomed, Inc.; Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc.; Mallinckrodt, LLC; Insys Therapeutics, Inc.; Mallinckrodt Plc; SpecGx; Allergan Plc f/k/a Actavis PLC; Watson Pharmaceuticals, Inc.; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma. Inc.; Anda, Inc.; H.D. Smith, LLC f/k/a H.D. Smith Wholesale Drug Co.; Henry Schein, Inc.; Miami-Luken, Inc.; AmerisourceBergen Drug Corporation; Cardinal Health, Inc.; CVS Health Corporation; The Kroger Co.; Rite-Aid Of Maryland, Inc.; Walgreens Boots Alliance, Inc.; Walmart, Inc.; McKesson Corporation; Richard Sackler; Beverly Sackler; David Sackler; Ilene Sackler Lefcourt; Jonathan Sackler; Kathe Sackler; Mortimer D.A. Sackler; Theresa Sackler; John Stewart; Mark Timney; Craig Landau; Russell Gasdia; and DOES 1-100 (collectively “Defendants”) under federal and state RICO laws, consumer protection statutes, and the common

¹ Sam Quinones, *Dreamland: The True Tale of America’s Opiate Epidemic* at 133 (Bloomsbury Press 2015) (hereinafter referred to as “Dreamland”).

law of nuisance, negligence, fraud, unjust enrichment, and civil conspiracy, seeking judgment against Defendants and in favor of Plaintiffs; compensatory damages; treble damages; punitive damages; pre-judgment and post-judgment interest; cost of suit; equitable relief, including injunctive relief, and all other relief to which they may be entitled and alleges as follows:

I. INTRODUCTION

1. Plaintiffs are operators of general acute care hospitals. Plaintiffs are dedicated to providing quality healthcare for local residents and contribute to the economic development of their communities. Based on the unique needs of each community served, these hospitals offer a wide range of diagnostic, medical and surgical services in inpatient and outpatient settings.

2. The communities served by Plaintiffs have been severely impacted by the opioid epidemic. Over the years, Plaintiffs have responded to the unique but changing demands of healthcare in the communities they serve. But the opioid epidemic has challenged their leadership skills, taxed their resources, and threatened their ability to provide quality health care to all in need. Additionally, as a result of the Emergency Medical Treatment and Labor Act (“EMTALA”), 42 U.S.C. § 1395dd (which requires hospital to provide emergency care in certain circumstances) Plaintiffs’ emergency rooms have been and continue to be the front door to the effects of the opioid epidemic.

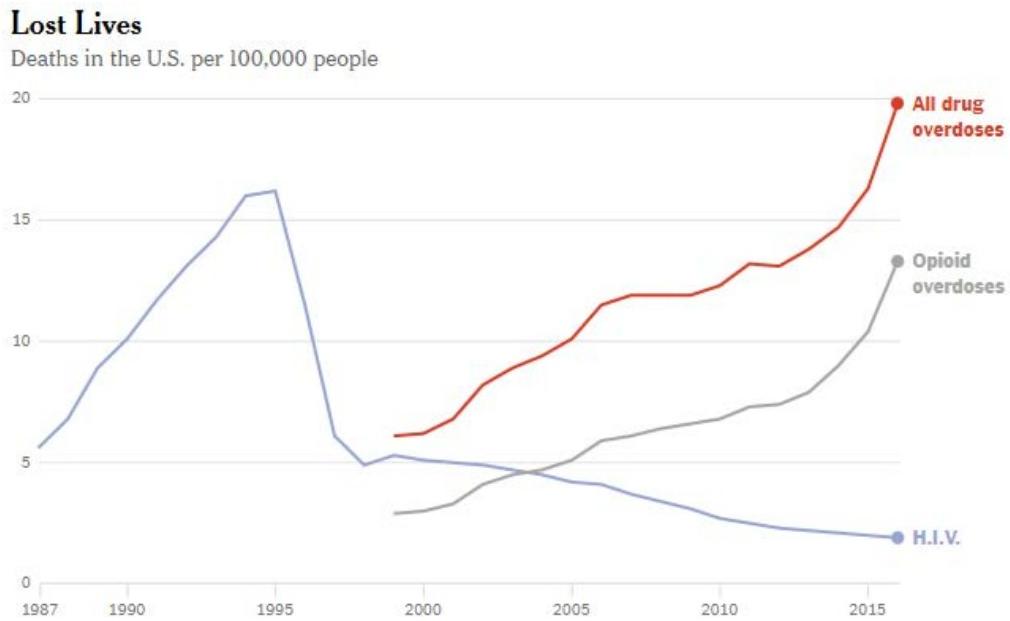
A. The Opioid Crisis

3. The United States is in the midst of an opioid epidemic caused by Defendants’ unlawful marketing, sale, and distribution of prescription opioids that has resulted in addiction, criminal activity, serious health issues, and loss of life.² According to the Centers for Disease

² As used herein, the term “opioid” refers to the entire family of opiate drugs including natural, synthetic, and semi-synthetic opiates.

Control (“CDC”), from 1999 to 2014, the sales of prescription opioids in the U.S. nearly quadrupled, but there was no overall change in the amount of pain that Americans reported.³

4. According to the CDC, opioid overdoses killed more than 45,000 people over a 12-month timeframe that ended in September 2017. It is already the deadliest drug epidemic in American history.⁴ If current trends continue, lives lost from opioid overdoses will soon represent the vast majority of all drug overdose deaths in the United States.



Note: Drug overdose data available since 1999. Source: Centers for Disease Control and Prevention | By THE NEW YORK TIMES.⁵

5. Between the start of the century and the year 2014, opioid-related death rates have increased by 200%, with 14% of that increase occurring between 2013 and 2014.⁶

³ Centers for Disease Control and Prevention, *Prescribing Data*, available at <https://www.cdc.gov/drugoverdose/data/prescribing.html>, (last accessed August 1, 2018).

⁴ The Editorial Board, *An Opioid Crisis Foretold*, THE NEW YORK TIMES (April 21, 2018), <https://www.nytimes.com/2018/04/21/opinion/an-opioid-crisis-foretold.html>.

⁵ *Id.*

⁶ *Id.*

6. The opioid epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”⁷ In many cases, heroin abuse starts with prescription opioid addiction.

7. According to the CDC, the United States is currently seeing the highest overdose death rated ever recorded.⁸ As opioid-related deaths have increased, the life expectancy in the United States has decreased.⁹

8. On October 28, 2017, the President of the United States declared the opioid crisis a public health emergency.¹⁰

9. On the demand side, the Defendants who manufacture, sell and market prescription opioid painkillers (the “Marketing Defendants”) purposefully, knowingly, and recklessly precipitated the crisis. These opioids have various brand names and generic names, and include OxyContin, fentanyl, hydrocodone, oxycodone, and others mentioned in this Complaint. Through a massive marketing campaign premised on false and incomplete information, the Marketing Defendants engineered a dramatic shift in how and when opioids are prescribed by the medical community and used by patients. The Marketing Defendants relentlessly and methodically—but

⁷ See Robert M. Califf, et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. End. J. Med. 1480 (Apr. 14, 2016), doi: 10.1056/NEJMsr1601307, <https://www.nejm.org/doi/full/10.1056/NEJMsr1601307>.

⁸ Jessica Glenza, *Opioid crisis: overdoses increased by a third across US in 14 months, says CDC*, THE GUARDIAN (March 6, 2018). <https://www.theguardian.com/us-news/2018/mar/06/opioid-crisis-overdoses-increased-by-a-third-across-us-in-14-months-says-cdc>.

⁹ National Center for Health Statistics, Life Expectancy, available at <https://www.cdc.gov/nchs/fastats/life-expectancy.htm>, (last accessed August 1, 2018); Centers for Disease Control and Prevention, U.S. drug overdose deaths continue to rise; increase fueled by synthetic opioids, (March 18, 2018), <https://www.cdc.gov/media/releases/2018/p0329-drug-overdose-deaths.html>.

¹⁰ Julie Hirschfeld Davis, *Trump Declares Opioid Crisis a ‘Health Emergency’ but Requests No Funds*, THE NEW YORK TIMES (Oct. 26, 2017), <https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html>.

untruthfully—asserted that the risk of addiction was low when opioids were used to treat chronic pain and overstated the benefits and trivialized the risk of the long-term use of opioids.

10. The Marketing Defendants' goal was simple: dramatically increase sales by convincing doctors to prescribe opioids not only for the kind of severe pain associated with cancer or short-term post-operative pain, but also for common chronic pain, such as back pain and arthritis. They did this even though they knew that opioids were addictive and subject to abuse, and that their claims regarding the risks, benefits, and superiority of opioids for long-term use were untrue and unfounded.

11. The Marketing Defendants' material misrepresentations and omissions were passed on from deceived prescribers to patients as intended. For instance, patients in substance abuse treatment whose addiction began with prescriptions for opioids to treat chronic pain often have reported that they were not warned of the risk that they might become addicted. A 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.¹¹

12. The Distributor Defendants saw the profit potential in opioid sales, participated in the conspiracy by ignoring their legal responsibilities under the Controlled Substance Act, and flooded affected areas with opioids while knowing they were contributing to, but profiting from, widespread addiction, human misery, and death.

13. Defendants succeeded. Opioid abuse has quickly become one of the nation's most pressing health management issues, not only because of its toll on patients, but increasingly

¹¹ Hazelden Betty Ford Foundation, *Missed Questions, Missed Opportunities*, (Jan. 27, 2016), available at <https://www.hazeldenbettyford.org/about-us/news-media/press-release/2016-doctors-missing-questions-that-could-prevent-opioid-addiction>, (last accessed Nov. 11, 2018).

because of the financial impact on hospitals and the rest of the healthcare system.¹²

14. The Marketing Defendants and Supply Chain Defendants extract billions of dollars of revenue from the addicted American public while hospitals sustain tens of millions of dollars in losses caused as a result of the direct and reasonably foreseeable consequences of the prescription opioid addiction epidemic. In fact, Defendants depend on hospitals to mitigate the health consequences of their illegal activities – at no cost to Defendants – thereby permitting Defendants to perpetuate their wrongful scheme. Defendants knew that but for the hospitals providing a safety net, the number of overdose deaths and other related health consequences arising from opioid addictions would have been far greater than actually occurred, and the public outcry and political backlash threatening their profitmaking activities would have been swifter and far more certain.

15. The deceptive marketing campaign of the Marketing Defendants and Distributor Defendants substantially contributed to an explosion in the use of opioids across the country. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include a prescription of an opioid.¹³

16. The sharp increase in opioid use resulting from Defendants' conduct has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that

¹² Jennifer Bresnick, *Hospitals Face Higher Costs, More ED Visits from Opioid Abuse*, HealthIT Analytics (Dec. 21, 2016), <https://healthitanalytics.com/news/hospitals-face-higher-costs-more-ed-visits-from-opioid-abuse> (last accessed on Feb.15, 2019).

¹³ Shefali Luthra, *Opioid Epidemic Fueling Hospitalizations, Hospital Costs*, KAISER HEALTH NEWS (May 2, 2016), available at <https://khn.org/news/opioid-epidemic-fueling-hospitalizations-hospital-costs/>

“aggressive marketing by pharmaceutical companies” is “likely to have contributed to the severity of the current prescription drug abuse problem.”¹⁴

17. In August 2016, then U.S. Surgeon General Vivek Murthy published an open letter to physicians nationwide, enlisting their help in combating this “urgent health crisis” and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the “devastating” results that followed, had “coincided with heavy marketing to doctors [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain.”¹⁵

18. In a 2016 report, the CDC explained that “[o]pioid prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses.”¹⁶ Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”¹⁷

19. Defendants’ practice of continually filling opioid prescriptions, including from suspicious prescribers, and failing to report suspicious orders of opioids has enabled an oversupply of opioids to communities, including communities in the regions that Plaintiffs serve. The Distributor Defendants had financial incentives to distribute higher volumes of opioids and not

¹⁴ *America’s Addiction to Opioids: Heroin and Prescription Drug Abuse*, U.S. Senate, Caucus on International Narcotics Control, 113th Cong., at 3 (May 14, 2014) (statement). Testimony of Dr. Nora D. Volkow, Director, National Institute on Drug Abuse, available at <https://www.hdsr.ord/?abstract&did=754557>.

¹⁵ Letter from Vivek H. Murthy, M.D., U.S. Surgeon General, available at <http://www.turntheriderx.org/> (last accessed July 23, 2018).

¹⁶ Rose A. Rudd, et al., Centers for Disease Control and Prevention, Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014 (Jan. 1, 2016), *Morbidity and Mortality Weekly Report*, 64(50);1378-82, available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm>.

¹⁷ *Id.*

report suspicious orders or guard against diversion. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit.

20. Further, either explicitly or implicitly, all Defendants in this action worked together to stifle the reporting of suspicious orders. This is because even one defection and reporting to the DEA could have reduced the overall quantity of opioids allowed to be dispensed within the United States. Therefore, to ensure that profits remained artificially high, the Defendants worked together to ensure oversupply of the market.

21. The widespread use of opioids and corresponding increase in addiction and abuse have led to increased emergency room visits, emergency responses to overdoses, and emergency medical technicians' administration of naloxone—the antidote to opioid overdose.

22. Opioids have endangered public health even beyond addiction, overdose and death. Intravenous use of opioids, which has been a particular problem with easy-to-inject Opana ER, has led to a surge in hepatitis C and created a risk of an even broader epidemic.

23. Carfentanil, a powerful derivative of fentanyl, has increasingly been found in heroin and fentanyl sold illicitly. Carfentanil is so strong that is typically used in veterinary medicine to sedate elephants and has been researched as a chemical weapon. A dose the size of a grain of salt can rapidly lead to deadly overdose in humans. “People have to understand there’s absolutely zero

use for humans. None. There's no use in humans unless you're trying to kill them.”¹⁸

24. Children are especially vulnerable to the opioid epidemic. Nationally, the rate of American children born with neonatal abstinence syndrome (“NAS”) quadrupled over the past 15 years. After birth, these infants will spend weeks in neonatal intensive care units while they painfully withdraw from the drugs, experiencing a multitude of symptoms including tremors and seizures—a process so painful that it traps many adults on opioids. Even after being released from the hospital, some children may still have to be treated with medication and physical therapy. It can cost upwards of \$60,000 to treat one baby.¹⁹ Children are also injured by the removal from their homes due to opioid abuse and addiction.

25. Throughout the nation, families and communities face heartbreakening tragedies that cannot be adequately conveyed by statistics, and they have faced them all too often. Many grieving families have been financially tapped out by the costs of repeated cycles of addiction treatment programs; others have lost hope and given up. The increasing number of cases takes both a physical and mental toll on investigators, first-responders, and hospitals such as Plaintiffs.

B. Impact Of Opioids On Hospitals

26. Hospitals—legally and morally—are compelled to act and treat patients with opioid-related conditions²⁰ and, as a result, are directly and monetarily damaged by the opioid

¹⁸ Evan Schriber, *Carfentanil Death Has Law Enforcement Warning of Danger*, TUCSON NEWS NOW (Apr. 16, 2018) available at <http://www.tucsonnewsnow.com/story/37971249/carfentanil-death-has-law-enforcement-warning-of-danger> (last accessed July 23, 2018).

¹⁹ Rappleye, et al., *Born Addicted: The Number of Opioid-Addicted Babies is Soaring*, NBC NEWS (Oct. 9, 2017), available at <https://www.nbcnews.com/storyline/americas-heroin-epidemic/born-addicted-number-opioid-addicted-babies-soaring-n806346>.

²⁰ “Opioid-related conditions” include but are not limited to opioid addiction and overdose; psychiatric and mental health treatment; NAS or other opioid-related conditions of newborns; illnesses associated with opioid use, such as endocarditis, hepatitis C, and HIV; surgical procedures that are more complex and expensive due to opioid addiction; illnesses or conditions claimed by a person with opioid addiction in order to obtain an opioid prescription; and any other condition identified in Plaintiffs’ records as related to opioid use and abuse.

epidemic. In addition to the cost of the opioid drugs themselves, hospitals have incurred and continue to incur millions of dollars in damages for the costs of uncompensated care as a result of the unlawful marketing, distribution, and sale of opioids. Arguably, more than any other institution, hospitals directly and monetarily bear the brunt of the opioid crisis. Plaintiffs are struggling from the relentless and crushing financial burdens caused by the epidemic of opioid addiction.

27. The effects of the opioid epidemic on hospitals may soon become even worse. The coverage rules under the Affordable Care Act (“ACA”) are in transition, thus creating the possibility of increased costs for hospitals for treatment of opioid-addicted patients admitted under EMTALA.²¹

28. Plaintiffs encounter patients with opioid addiction on a daily basis. They must deal with patients who have serious medical conditions that require extra care and expense because the patient is addicted to opioids.

29. The statistics are startling. Adult hospitalizations due substantially to opioid-related medical conditions doubled from 2000 to 2012. From 2005 to 2014, emergency department visits exhibited a 99.4% cumulative increase.²²

30. Between 2005 and 2014 there was a dramatic increase nationally in hospitalizations involving opioids: the rate of opioid-related inpatient stays increased 64%, and the rate of opioid-related emergency department (“ED”) visits nearly doubled.²³

²¹ American Hospital Association, *AHA Priorities to Address the Opioid Crisis*, <https://www.aha.org/guidereports/2018-03-02-aha-priorities-address-opioid-crisis>, (last accessed Aug. 1, 2018).

²² *Id.*

²³ Audrey J. Weiss, et al., *Patient Characteristics of Opioid-Related Inpatient Stays and Emergency Department Visits Nationally and by State, 2014* (June 2017), <https://www.hcup-us.ahrq.org/reports/statbriefs/2017/2017-06-01-0001.pdf>

31. The average health care costs for those diagnosed with an opioid use disorder were eight times higher than those without an opioid use disorder.²⁴

32. The cost to hospitalize those with opioid addiction has more than tripled in a decade, up to nearly \$15 billion in 2012. Similarly, the number of patients hospitalized due to the effects of these drugs surged by more than 72% in 2012, although overall hospitalizations during that time stayed relatively flat.²⁵

33. Private insurance covers only a portion of those costs. The burden is carried by hospitals, patients, and government programs.²⁶ In 2012, hospitals provided almost \$15 billion for opioid-related inpatient care, more than double of what they billed in 2002.²⁷ A substantial portion of these costs were under-insured or unreimbursed.

34. In 2012, an average hospital stay for a patient with an opioid-related condition cost about \$28,000 and only about 20% of the discharges related to those incidents were covered by private insurance. The number increased to \$107,000 if there was an associated infection, with merely 14% covered by insurance.²⁸

us.ahrq.gov/reports/statbriefs/sb224-Patient-Characteristics-Opioid-Hospital-Stays-ED-Visits-by-State.pdf.

²⁴ Alen G. White, PhD, et al., *Direct Costs of Opioid Abuse in an Insured Population in the United States*, published in Journal of Managed Care Pharmacy, Vol. 11, No. 6 July/August 2005, at 469.

²⁵ Marty Stempniak, *Opioids Add to a Sharp Rise in Hospitalizations, Costs*, (May 5, 2016), <https://www.hhnmag.com/articles/7231-opioids-contribute-to-a-sharp-rise-in-hospitalizations-health-care-costs>, (last accessed on July 11, 2018).

²⁶ *Id.*

²⁷ Shefali Luthra, *Opioid Epidemic Fueling Hospitalizations, Hospital Costs*, KAISER HEALTH NEWS (May 2, 2016), <https://khn.org/news/opioid-epidemic-fueling-hospitalizations-hospital-costs/>.

²⁸ *Id.*

35. Patients with complex opioid addiction-related histories (medically and psychosocially) often cannot get treatment at skilled nursing facilities if they are discharged by hospitals.

36. The cost of treating opioid overdose victims in hospital intensive care units jumped 58% in a seven-year span. Between 2009 and 2015, the average cost of care per opioid overdose admission increased from \$58,000 to \$92,400. This was during a period where the overall medical cost escalation was about 19%. This cost increase also highlights a troubling trend: overdose patients are arriving in worse shape, requiring longer stays and a higher level of treatment.²⁹

37. Pregnant women and their children have been significantly impacted by the opioid epidemic. There are negative consequences of drug use for pregnant women including increased risks of assault and abuse, miscarriage, and contracting hepatitis or HIV. Each year, thousands of infants are exposed to opioids while in the womb. Infants who are chronically exposed to opioids and other drugs will often experience a constellation of withdrawal signs after birth, collectively referred to as NAS.

38. The rates of opioid abuse during pregnancy have increased nationally and in the regions served by Plaintiffs. From 2002 to 2013, the rate of NAS in the U.S. increased 300%. The misrepresentations of Marketing Defendants, Distributor Defendants, and others led area health care providers to prescribe, patients to take, and payors to cover opioids for the treatment of chronic pain. Through their marketing, the Marketing Defendants and Distributor Defendants overcame barriers to widespread prescribing of opioids for chronic pain with deceptive messages about the risks, benefits, and sustainability of long-term opioid use. These harms were compounded by supplying opioids beyond what the market could bear, funneling so many opioids into many hard-

²⁹ Casey Ross, *The Cost of Treating Opioid Overdose Victims is Skyrocketing*, STAT NEWS (August 11, 2017), <https://www.statnews.com/2017/08/11/opioid-overdose-costs/>.

hit communities that the only logical conclusion was that the product was being diverted and used illicitly. The massive quantities of opioids that flooded into the areas served by Plaintiffs as a result of Defendants' wrongful conduct has devastated communities across the country.

C. Financial Impact Of Defendants' Activities On Plaintiffs

39. Plaintiffs have treated, and continue to treat, numerous patients for opioid-related conditions, including: (1) opioid overdose; (2) opioid addiction; (3) hepatitis C, HIV and other infections occurring as a result of intravenous drug use; (4) neonatal treatment in its NICU for babies born opioid-dependent, for which treatment is specialized, intensive, complex, lengthy, and highly expensive; and (5) psychiatric and related treatment for patients with opioid addiction who present in need of mental health treatment programs.

40. Plaintiffs have incurred and continue to incur substantial unreimbursed costs for its treatment of patients with opioid-related conditions. These patients with opioid-related conditions seek treatment from Plaintiffs as a direct and proximate result of the opioid epidemic created and engineered by Defendants. As a result, Plaintiffs' monetary losses with respect to treatment of these patients were and are direct and foreseeable to Defendants and were and are the direct and proximate result of Defendants' acts and omissions specified herein.

41. Plaintiffs also have incurred and continue to incur operational costs in the form of surgical procedures and other care that have been and are more complex and expensive than would otherwise be the case if the patients were not opioid affected. Surgical procedures on opioid affected patients have been and are complicated and costly and require special protective measures and related prescription drugs.

42. Additionally, individuals with opioid addiction have presented and continue to present themselves to Plaintiffs claiming to have illnesses and medical problems in an effort to

obtain opioids. Plaintiffs have incurred and continue to incur operational costs related to the time and expenses in diagnosing, testing, and otherwise attempting to treat these individuals.

43. The costs incurred by Plaintiffs are the direct and proximate result of the False Narrative campaign described below and the opioid epidemic created and engineered by Defendants.

44. Because opioids are dangerous and highly addictive drugs, it was direct and foreseeable to Defendants that the increase in the use of opioids would result in a corresponding epidemic of patients with opioid-related conditions going to hospitals for treatment, including to Plaintiffs. It was direct and foreseeable to Defendants that Plaintiffs would suffer substantial monetary losses because of the opioid epidemic, because hospitals are on the front line of treatment for these patients and must bear the additional costs of treatment.

45. It was also direct and foreseeable that Defendants would face claims from hospitals for their costs from treating opioid-related conditions.

46. Plaintiffs have purchased and continue to purchase and administer opioids marketed and sold by Defendants. Defendants have marketed and continue to market their opioid products directly to Plaintiffs, their pharmacy representatives, and their doctors. Defendants directly marketed their opioid products through the False Narrative described below. Plaintiffs are direct customers and victims of Defendants' false, deceptive, and unfair marketing of opioids described hereafter.

47. Plaintiffs have purchased opioids from Defendants, have used them as falsely and deceptively marketed by Defendants, and have suffered damages as a direct and proximate result of Defendants' acts and omissions as described in this Complaint.

48. Plaintiffs bring this civil action to recover monetary losses that they have incurred as a direct and proximate result of Defendants' false, deceptive, and unfair marketing of prescription opioids. Such economic damages were foreseeable to Defendants and were sustained because of Defendants' unlawful actions and omissions.

49. Plaintiffs bring this suit against the manufacturers of prescription opioids. The manufacturers aggressively pushed highly addictive, dangerous opioids, falsely representing to doctors that patients would only rarely succumb to drug addiction. These pharmaceutical companies aggressively advertised to and persuaded hospitals and their doctors to purchase and prescribe highly addictive, dangerous, opioids and turned patients into drug addicts for their own corporate profit. Such actions were unlawful.

50. Plaintiffs also bring this suit against the wholesale distributors of these highly addictive drugs. In addition to participating in the False Narrative campaign described below, the Distributor Defendants (along with the Manufacturers) unlawfully breached their legal duties under state law to monitor, detect, investigate, report, and refuse to fill suspicious orders of prescription opiates, which enabled the manufacturers' deceptive advertising to increase sales, profits and distribution of their products to hospitals, including Plaintiffs.

D. The Roles of Defendants in Causing and Perpetuating the Opioid Crisis

51. The Marketing Defendants' push to increase opioid sales worked. Through publications and websites, endless streams of sales representatives, "education" programs, and other means, the Marketing Defendants dramatically increased their sales of prescription opioids and reaped billions of dollars of profit as a result. Since 1999, the amount of prescription opioids sold in the U.S. has nearly quadrupled. In 2016, 289 million prescriptions for opioids were filled in the U.S.—enough to medicate every adult in America around the clock for a month.

52. On the supply side, the crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers and distributors, who failed to maintain effective controls over the distribution of prescription opioids, and who instead have actively sought to evade such controls. Defendants have contributed directly, foreseeably, and substantially to the opioid crisis by selling and distributing far greater quantities of prescription opioids than they know should be necessary for legitimate medical uses, while failing to report, and take steps to halt, suspicious orders when they were identified, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

53. From the day they made the pills to the day those pills were consumed in each community, the Marketing Defendants had control over the information regarding addiction they chose to spread and emphasize as part of their massive marketing campaign. By providing misleading information to doctors about addiction being rare and opioids being safe even in high doses, then pressuring those doctors into prescribing their products by arguing, among other things, that no one should be in pain, especially chronic pain, the Marketing Defendants created a population of addicted patients who sought opioids at never-before-seen rates. The scheme worked, although perversely, and through it the Marketing Defendants caused their profits to soar as more and more people became dependent on opioids.

54. Defendants systematically and repeatedly disregarded the health and safety of the public. Charged by law to monitor and report dangerous behavior, they failed to do so in favor of maximizing corporate profits and increasing their market share.

55. Corporate greed and callous indifference to the known, serious potential for human suffering and death have caused this public health crisis. Defendants unleashed a healthcare crisis

that has had far-reaching financial and social consequences in this country, including opioid addiction and death.

56. The Marketing Defendants falsely and misleadingly, and contrary to the language of their drugs' labels: (1) downplayed the serious risk of addiction; (2) promoted the concept of "pseudo addiction" and thus advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; (6) promoted the falsehood that long-term opioid use improves functioning; (7) misrepresented the effectiveness of time-released dosing, and, in particular, the effectiveness of a version of OxyContin that purportedly provided twelve hours of pain relief; and (8) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse, addiction and death.

57. The Marketing Defendants disseminated these common messages to reverse the popular and medical understanding of opioids. They disseminated these messages directly, through their sales representatives, and in speaker groups led by physicians who were recruited by and paid by the Marketing Defendants for their support of the Marketing Defendants' marketing messages.

58. The Marketing Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("KOLs") and (b) creating, funding, assisting, directing, and/or encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups"). The Marketing Defendants then worked together with those KOLs and Front Groups to profoundly influence, and at times control, the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, continuing medical education ("CME") programs, medical conferences and seminars, and scientific articles. Thus, working individually

and collectively, and through these Front Groups and KOLs, the Marketing Defendants persuaded doctors and patients that what they had long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids.

59. Each Marketing Defendant knew that its misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of each Defendant's misrepresentations has been confirmed by the U.S. Food and Drug Administration ("FDA") and the CDC, including by CDC's *Guideline for Prescribing Opioids for Chronic Pain*, issued in 2016 and approved by the FDA.³⁰

II. JURISDICTION AND VENUE

60. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 based upon the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.* ("RICO"). This Court has supplemental jurisdiction over Plaintiffs' state law claims pursuant to 28 U.S.C. § 1337, because those claims are so related to Plaintiffs' federal claims that they form part of the same case or controversy.

61. To the extent such a showing is necessary, the Court has personal jurisdiction over Defendants because (1) at all relevant times Defendants engaged in substantial business activities in Ohio and purposefully directed their actions towards Ohio, voluntarily submitted to the jurisdiction of Ohio when obtaining a manufacturer or distributor license, and have the requisite minimum contacts with Ohio necessary to constitutionally permit this Court to exercise

³⁰ See Centers for Disease Control and Prevention, *Guideline for Prescribing Opioids For Chronic Pain*, https://www.cdc.gov/drugoverdose/pdf/guidelines_factsheet-a.pdf (last accessed Aug. 1, 2018); Pat Anson, *FDA Endorses CDC Opioid Guidelines*, PAIN NEWS NETWORK (Feb. 4, 2016), <https://www.painnewsnetwork.org/stories/2016/2/4/fda-endorses-cdc-opioid-guidelines>.

jurisdiction, and (2) the Court may, under 18 U.S.C. § 1965(b), exercise nationwide jurisdiction over the named Defendants where the “ends of justice” require national service and Plaintiffs demonstrate national contacts. Here, the “interests of justice,” including judicial economy, avoiding conflicting decisions, rationales and results, uniformity or just outcomes require that Plaintiffs be allowed to bring all members of the nationwide RICO enterprise before the court in a single trial.

62. To the extent such a showing is necessary, venue is proper in this District (1) under 28 U.S.C. § 1391(b)(2), because a substantial part of the events and omissions giving rise to Plaintiffs’ claims occurred in this judicial district, and (2) under 28 U.S.C. §§ 1391(b)(1) and (c)(2), because all the Defendants are subject to personal jurisdiction in this state and in this judicial district, such that Defendants are deemed to reside in this state and in this judicial district.

III. PARTIES

A. Plaintiffs

63. Plaintiff St. Vincent Charity Medical Center (“St. Vincent”) is an Ohio nonprofit corporation, with its principal place of business in Cleveland, Ohio. “Rosary Hall” is a registered trademark of St. Vincent.

64. Plaintiff Infirmary Health Hospitals, Inc. (“Infirmary Health) is a private non-profit corporation organized under the laws of the State of Alabama, with its principal place of business in Alabama.

65. Plaintiff Monroe County Healthcare Authority (“Monroe”), d/b/a Monroe County Hospital, is a public corporation organized under the laws of the State of Alabama, with its principal place of business in Alabama.

66. Plaintiff Southwest Mississippi Regional Medical Center is a public non-profit corporation organized under the laws of the State of Mississippi, with its principal place of business in Mississippi.

B. Defendants

1. Marketing Defendants

a. Purdue, Associated Companies and Associated Individuals

67. Defendant Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

68. Defendant Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut, and is the general partner of Purdue Pharma, L.P.

69. Defendant the Purdue Frederick Company, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., and The Purdue Frederick Company, Inc. are collectively referred to as "Purdue."

70. The following Defendants, all members of the Sackler family that beneficially owns Purdue, have served on the Board of Purdue during the relevant times indicated in parenthesis:

- a. Richard Sackler (at all pertinent times until 2018³¹), a resident of Florida;
- b. Beverly Sackler (all pertinent times until 2017), a resident of Connecticut;
- c. David Sackler (2012-18), a resident of New York;
- d. Ilene Sackler Lefcourt (all pertinent times), a resident of New York;
- e. Jonathan Sackler (all pertinent times), a resident of Connecticut;
- f. Kathe Sackler (all pertinent times), a resident of Connecticut;

³¹ Defendant Beverly Sackler left the Board in 2017. Defendants Richard, David and Theresa Sackler left the Board in 2018. Defendants Jonathan Sackler, Ilene Sackler Lefcourt, Kathe Sackler, and Mortimer Sackler remain on the Board.

- g. Mortimer D.A. Sackler (all pertinent times), a resident of New York³²; and
- h. Theresa Sackler (all pertinent times until 2018), a resident of the United Kingdom.

The foregoing Defendants (collectively, the “Sackler Defendants”) controlled Purdue’s misconduct. Each of them took a seat on the Board of Directors of Purdue Pharma Inc. Together, the Sackler Defendants, at all pertinent times, constituted a majority of Board, which gave them full power over Purdue. They directed and otherwise participated in Purdue’s deceptive sales and marketing practices, sending hundreds of orders to executives and other employees.

71. Defendants John Stewart (CEO from 2007 to 2013), a resident of Florida, Mark Timney (2014 to 2017), a resident of Connecticut, and Craig Landau (2017 to the present), a resident of Connecticut, each directed Purdue’s deception as CEO of Purdue Pharma Inc. and Purdue Pharma L.P. Defendant Russell Gasdia, a resident of Massachusetts, carried out the misconduct as Vice President of Sales and Marketing at all pertinent times until June 2014. The Defendants named in this paragraph are collectively referred to as the “Purdue Officer Defendants.” The Sackler Defendants and the Purdue Officer Defendants are collectively referred to as the “Purdue Individual Defendants.” Purdue and the Purdue Individual Defendants are collectively referred to as the “Purdue Defendants.”

72. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States, including to Plaintiffs. OxyContin is Purdue’s best-selling opioid. Since 2009, Purdue’s annual nationwide sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-

³² References to Mortimer Sackler in this Complaint are to Mortimer David Alfons Sackler. Mortimer Sackler’s father, the late Mortimer D. Sackler, was also involved in Purdue Pharma during his lifetime.

fold from its 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

73. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States \$635 million – one of the largest settlements with a drug company for marketing misconduct. In the same year, Purdue settled with 27 states for its Consumer Protection Act violations regarding the Purdue's extensive off-label marketing of OxyContin and Purdue's failure to adequately disclose abuse and diversion risks associated with the drug. Substantially all of the Sackler Defendants (all of those except David Sackler) were heavily involved in the conduct that led to the fines and criminal convictions in 2007. The misconduct of Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler was particularly unfair, deceptive, unreasonable, and unlawful because they already had been given a second chance. From the 1990s until 2007, they directed a decade of misconduct, which led to criminal convictions, a judgment of this Court, and commitments that Purdue would not deceive doctors and patients again. That background confirms that their misconduct since 2007 was knowing, purposeful, reckless, and intentional.

74. None of this stopped Purdue and the Purdue Individual Defendants. In fact, Purdue continued to create the false perception that opioids were safe and effective for long-term use, even after being caught using unbranded marketing methods to circumvent the system. In short, Purdue paid the fine when caught and then continued business as usual, deceptively marketing and selling billions of dollars of opioids each year.

75. While the Sackler Defendants relinquished their officer titles in or around 2003 to try to shield themselves from future criminal and civil liability, they remained Purdue's owners, in control of its Board of Directors, and thus in firm control.

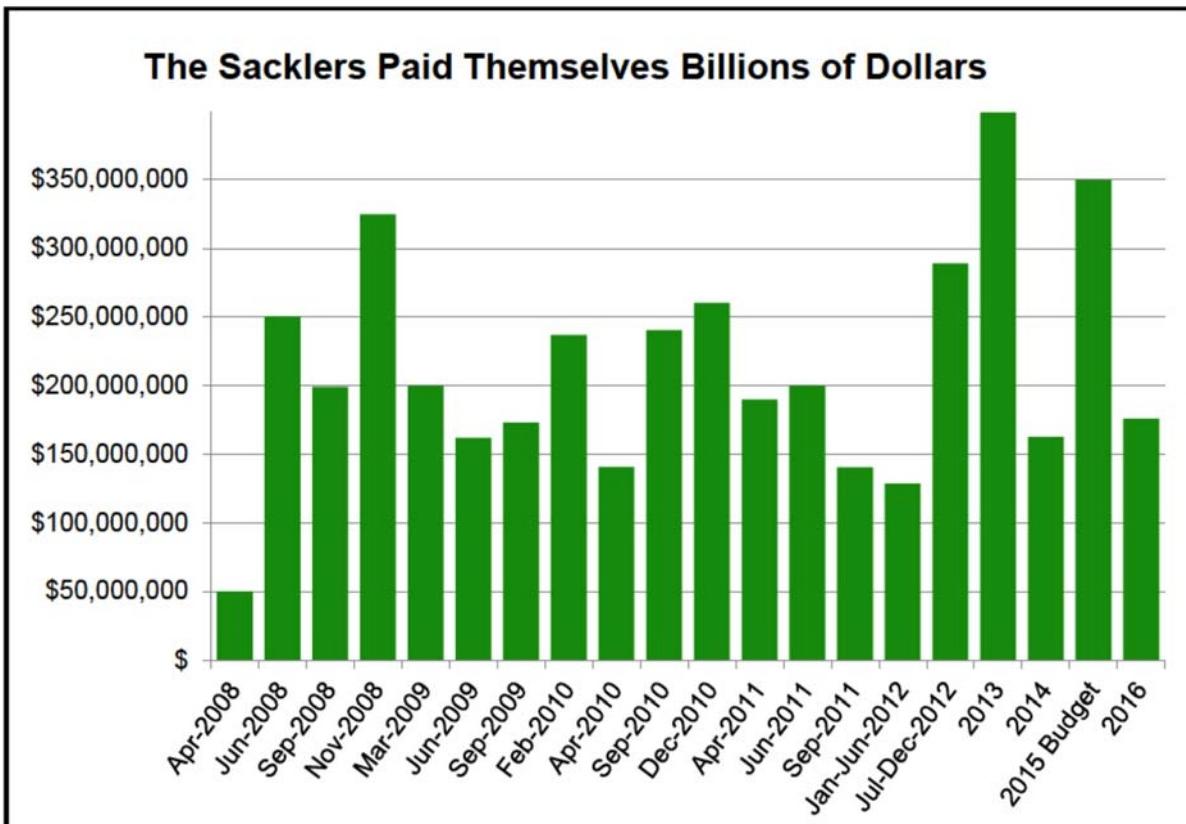
76. At all relevant times, at least through the end of 2018, the Sackler Defendants controlled Purdue's deceptive sales campaign. They directed the company to hire hundreds more sales representatives to visit doctors thousands more times. They insisted that sales representatives repeatedly visit the most prolific prescribers. They directed representatives to encourage doctors to prescribe more of the highest doses of opioids. They studied unlawful tactics to keep patients on opioids longer and then ordered staff to use them. They asked for detailed reports about doctors suspected of misconduct, how much money Purdue made from them, and how few of them Purdue had reported to the authorities. They sometimes demanded more detail than anyone else in the entire company, so staff had to create special reports just for them. Richard Sackler even went into the field to promote opioids to doctors and supervise representatives face-to-face. In connection with a single meeting in 2011, for example, sales and marketing staff scrambled to prepare responses to questions from the Sackler Defendants, Defendant Mortimer Sackler asked about launching a generic version of OxyContin to "capture more cost sensitive patients," Defendant Kathe Sackler recommended looking at the characteristics of patients who had switched to OxyContin to see if Purdue could identify more patients to convert, and Defendant Jonathan Sackler wanted to study changes in market share for opioids, focusing on dose strength.

77. The Sackler Defendants' micromanagement was so intrusive that staff begged for relief. Defendant Gasdia wrote to the CEO: "Anything you can do to reduce the direct contact of Richard into the organization is appreciated." To convince the Sackler Defendants to make him CEO, Defendant Landau wrote a plan that he titled: "SACKLER PHARMA ENTERPRISE." He started by admitting that the Sackler Defendants in fact controlled the company like chief executive officers. The family ran "the global Sackler pharmaceutical enterprise ... with the Board of Directors serving as the 'de-facto' CEO."

78. The Sackler Defendants concealed their extensive involvement at all costs. In 2000, the Sackler Defendants were warned that a reporter was “sniffing about the OxyContin abuse story.” The Sackler Defendants put the threat on the agenda for the next Board meeting and began covering their tracks. They planned a response that “deflects attention away from the company owners.” More recently, in November 2016, staff prepared statements to the press denying the Sackler Defendants’ involvement in Purdue. Their draft claimed: “Sackler family members hold no leadership roles in the companies owned by the family trust.” A staff member reviewing the draft knew what was up and commented with apparent sarcasm: “Love the … statement.” Staff eventually told the press: “Sackler family members hold no management positions.” Some employees worried about the deception. When journalists asked follow-up questions about the Sackler Defendants, communications staff deliberated about whether to repeat the “no management positions” claim. They double-checked that Purdue’s top lawyers had ordered the statement. Then they arranged for one of the Sackler Defendants’ foreign companies to issue it, so U.S. employees would not be blamed: “The statement will come out of Singapore.”

79. Most of all, the Sacklers cared about money. Millions of dollars were not enough. They wanted billions. They cared more about money than about patients, or their employees, or the truth. In 1999, when employee Michael Friedman reported to Richard Sackler that Purdue was making more than \$20,000,000 per week, Richard replied immediately, at midnight, that the sales were “not so great.” “After all, if we are to do 900M this year, we should be running at 75M/month. So it looks like this month could be 80 or 90M. Blah, humbug. Yawn. Where was I?” Missives of this nature from Richard Sackler to Purdue’s ostensible management were a routine, if not daily, occurrence. There was no such thing as enough.

80. From the money that Purdue collected as a result of its wrongful conduct, they paid themselves and their family billions of dollars. From the 2007 convictions (of certain Purdue officers) until 2018, the Sackler Defendants voted dozens of times to pay out Purdue's opioid profits to their family - in total ***more than four billion dollars.***



81. The Purdue Individual Defendants all actively participated in the common law torts and federal and state statutory violations of Purdue and benefited therefrom. The tortious conduct of the Purdue Individual Defendants was not, and could not have been through the exercise of due diligence, known to the public until their conduct was detailed in recent court filings by the Attorney General of Massachusetts.

b. Cephalon and Associated Companies

82. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania.

83. Defendant Teva Pharmaceutical Industries, Ltd. is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Pharmaceuticals Ltd. acquired Cephalon in October 2011, and Cephalon Inc. became a wholly owned subsidiary of Teva Pharmaceuticals Ltd.

84. Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a Delaware corporation with its principal place of business in North Wales, Pennsylvania, and is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd.

85. Teva USA and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva USA also sells generic opioids in the United States, including generic opioids previously sold by Allergan plc, whose generics business Teva Pharmaceutical Industries Ltd., Teva USA’s parent company based in Israel, acquired in August 2016. Teva USA and Cephalon, Inc. are collectively referred to herein as “Teva.”

86. Teva USA and Cephalon, Inc. worked together to manufacture, promote, sell, and distribute opioids such as Actiq and Fentora in the United States. Actiq has been approved by the FDA only for the “management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain.”³³ Fentora has been approved by the FDA only for the “management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent

³³ *Highlights of Prescribing information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII (2009), ACTIQ PI/Med Guide,* https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf (last accessed Aug. 1, 2018).

cancer pain.”³⁴ In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay a \$425 million fine.³⁵

87. Teva USA, and Cephalon, Inc. (collectively Cephalon) work together closely to market and sell Cephalon products in the United States. Since its acquisition of Cephalon in October 2011, Teva USA has conducted all sales and marketing activities for Cephalon in the United States, through its “specialty medicines” division. Teva USA holds out Actiq and Fentora as Teva products to the public. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

88. All of Cephalon’s promotional websites, including those for Actiq and Fentora, display Teva Ltd.’s logo.³⁶ Teva USA’s parent company, Teva Pharmaceuticals Industries, Ltd. lists Cephalon’s and Teva USA’s sales as its own on its financial reports, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to “the inclusion of a full year of Cephalon’s specialty sales,” including *inter alia* sales of Fentora.³⁷

89. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to herein as “Cephalon.”

³⁴ *Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII* (2011), https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf (last accessed August 1, 2018).

³⁵ Press Release, U.S. Dep’t of Justice, Biopharmaceutical Company, Cephalon, to Pay \$425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), <https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html>.

³⁶ E.g., ACTIQ, <http://www.actiq.com/> (displaying logo at bottom-left) (last accessed Aug. 1, 2018).

³⁷ Teva Ltd., Annual Report (Form 20-F), at 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.

90. From 2000 forward, Cephalon has made thousands of payments to physicians nationwide, including in Ohio, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, many of whom were not oncologists and did not treat cancer pain, but in fact to deceptively promote and maximize the use of opioids.

c. Janssen and Associated Companies

91. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

92. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of J&J.

93. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which was formerly known as Janssen Pharmaceutica, Inc.

94. Defendant Noramco, Inc. is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. Noramco, Inc. is or had been part of J&J's opium processing. It makes active pharmaceutical ingredients ("APIs") for opioid painkillers.

95. Johnson & Johnson is the only company that owns over 10% of Janssen Pharmaceuticals stock. J&J controls the sale and development of Janssen Pharmaceuticals drugs and Janssen Pharmaceuticals profits inure to J&J's benefit.

96. J&J, Janssen Pharmaceuticals, Inc., Noramco, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc. (collectively, "Janssen") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States.

97. Janssen manufactures, promotes, sells, and distributes drugs in the United States,

including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta (tapentadol) and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

98. Janssen made thousands of payments to physicians nationwide, including in Ohio, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

99. Janssen, like many other companies, has a corporate code of conduct, which sets forth the organization's mission, values and principles. Janssen's employees are required to read, understand and follow its Code of Conduct for Health Care Compliance. Johnson & Johnson imposes this code of conduct on Janssen as a pharmaceutical subsidiary of J&J.³⁸ Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. Janssen's website "*Ethical Code for the Conduct of Research and Development*," names only J&J and does not mention Janssen anywhere within the document. The "*Ethical Code for the Conduct of Research and Development*" posted on the Janssen website is J&J's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

100. The "*Every Day Health Care Compliance Code of Conduct*" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "*Pharmaceutical Companies of Johnson & Johnson*" and as one of the "*Johnson & Johnson Pharmaceutical Affiliates*." It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise

³⁸ Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, sales associates must certify that they have "read, understood and will abide by" the code. The code governs all of the forms of marketing at issue in this case. J&J made payments to thousands of physicians nationwide, including in Ohio, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

d. Endo and Associated Companies

101. Defendant Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

102. Defendant Endo Pharmaceuticals Inc. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

103. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. (collectively, "Endo") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States.

104. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, generic versions of oxycodone, oxymorphone, hydromorphone and hydrocodone in the United States. Opioids made up roughly \$403 million of Endo's overall revenues of \$3 billion in 2012. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. On June 8, 2017, the FDA requested that Endo remove Opana ER from the market because of a "serious outbreak" of HIV and hepatitis C due to abuse of the drug after the reformulation of Opana from a nasal spray

to an injectable.³⁹ In response to the FDA's request, Endo removed Opana ER from the market in July 2017, the first time the agency had ever moved to pull an opioid medication from sale.⁴⁰ Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

105. Endo made thousands of payments to physicians nationwide, including in Ohio, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

e. Insys Therapeutics, Inc.

106. Insys Therapeutics, Inc. is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys's principal product and source of revenue is Subsys.

107. Insys made thousands of payments to physicians nationwide, including to doctors in Ohio, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

108. Subsys is a transmucosal immediate-release formulation (TIRF) of fentanyl, contained in a single-dose spray device intended for oral, under the tongue administration. Subsys was approved by the FDA solely for the treatment of breakthrough cancer pain.

109. In 2016, Insys made approximately \$330 million in net revenue from Subsys.

³⁹ Press Release, U.S. Food & Drug Administration, FDA Requests Removal of Opana ER for Risks Related to Abuse (June 8, 2017),

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>.

⁴⁰ Press Release, Endo International PLC, Endo Provides update on Opana ER (July 6, 2017), <http://investor.endo.com/news-releases/news-release-details/endo-provides-update-apaner-er>.

110. Insys promotes, sells, and distributes Subsys throughout the United States and Ohio.

111. Insys's founder and owner was recently arrested and charged, along with other Insys executives, with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud insurance companies.

f. Abbott Laboratories

112. Defendant Abbott Laboratories is an Illinois corporation with its principal place of business in Abbott Park, Illinois. Defendant Abbott Laboratories, Inc. is a subsidiary of Abbott Laboratories, whose principal place of business is also in Abbott Park, Illinois. Defendants Abbott Laboratories and Abbott Laboratories, Inc. are referred to collectively as "Abbott."

113. Abbott was primarily engaged in the promotion and distribution of opioids nationally due to the co-promotional agreement with Defendant Purdue. Pursuant to that agreement, between 1996 and 2006, Abbott actively promoted, marketed, and distributed Purdue's opioid products as set forth above.

114. Abbott, as part of the co-promotional agreement, helped turn OxyContin into the largest selling opioid in the nation. Under the co-promotional agreement with Purdue, the more Abbott generated in sales, the higher the reward. Specifically, Abbott received twenty-five to thirty percent (25-30%) of all net sales for prescriptions written by doctors its sales force called on. This agreement was in operation from 1996-2002, following which Abbott continued to receive a residual payment of six percent (6%) of net sales up through at least 2006.

115. With Abbott's help, sales of OxyContin went from a mere \$49 million in its first full year on the market to \$1.2 billion in 2002. Over the life of the co-promotional agreement, Purdue paid Abbott nearly half a billion dollars.

116. Abbott and Purdue's conspiring with Pharmacy Benefit Managers (PBMs) to drive opioid use is well established. As described in an October 28, 2016, article from Psychology Today entitled *America's Opioid Epidemic*:

Abbott and Purdue actively misled prescribers about the strength and safety of the painkiller [OxyContin]. To undermine the policy of requiring prior authorization, they offered lucrative rebates to middlemen such as Merck Medco [now Express Scripts] and other pharmacy benefits managers on condition that they eased availability of the drug and lowered co-pays. The records were part of a case brought by the state of West Virginia against both drug makers alleging inappropriate and illegal marketing of the drug as a cause of widespread addiction.... One reason the documents are so troubling is that, in public at least, the drug maker was carefully assuring authorities that it was working with state authorities to curb abuse of OxyContin. Behind the scene, however, as one Purdue official openly acknowledged, the drug maker was "working with Medco (PBM) [now Express Scripts] to try and make parameters [for prescribing] less stringent.⁴¹

g. Amneal Pharmaceuticals, LLC

117. Defendant Amneal Pharmaceuticals, LLC ("Amneal") is a Delaware limited liability company with its principal place of in New Jersey. At all relevant times, Amneal has sold prescription drugs including opioids in Ohio and across the United States.

h. Depomed, Inc.

118. Defendant Depomed, Inc. ("Depomed") is a California corporation with its principal place of business in Newark, California. Depomed describes itself as a specialty pharmaceutical company focused on pain and other central nervous system conditions. Depomed develops, markets, and sells prescriptions drugs in Ohio and across the United States. Depomed acquired the rights to Nucynta and Nucynta ER for \$1.05 billion from Janssen pursuant to a January 15, 2015, Asset Purchase Agreement. This agreement closed on April 2, 2015.

⁴¹ American Society of Addiction Medicine, *America's Opioid Epidemic – Court released documents show drug makers blocked efforts to curb prescribing*, PSYCHOLOGY TODAY, Oct. 28, 2016, <https://www.psychologytoday.com/blog/side-effects/201610/america-s-opioid-epidemic>.

i. Mallinckrodt Entities

119. Defendant Mallinckrodt plc is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June of that year. Mallinckrodt plc also operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri.

120. Defendant Mallinckrodt LLC (together with Mallinckrodt plc and SpecGx LLC, “Mallinckrodt”) is a Delaware corporation with its headquarters in Hazelwood, Missouri.

121. Defendant SpecGx LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly owned subsidiary of Mallinckrodt plc.

122. Mallinckrodt manufactures, markets, sells and distributes pharmaceutical drugs throughout the United States, and to Plaintiffs. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

123. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc., a subsidiary of Covidien plc, acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

124. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the DEA's entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated, based on IMS Health⁴² data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.⁴³

125. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

126. Among the drugs Mallinckrodt manufactures or has manufactured are the following: Schedule II: Exalgo (Hydromorphone hydrochloride, extended release), Roxicodone (Oxycodone hydrochloride), Xartemis XR (Oxycodone hydrochloride and acetaminophen), Methadose (Methadone hydrochloride), generic morphine sulfate extended release, morphine sulfate oral solution, fentanyl transdermal system, oral transmucosal fentanyl citrate, oxycodone and acetaminophen, hydrocodone bitartrate and acetaminophen, hydromorphone hydrochloride, Hydromorphone hydrochloride, extended release, oxymorphone hydrochloride, methadone hydrochloride. Schedule III: buprenorphine and naloxone. Unscheduled: naltrexone hydrochloride.

⁴² "IMS Health was a [provider of] information, services and technology for the healthcare industry, including U.S. physician prescribing data." It has changed its corporate form and is now known as "IQVIA."

⁴³ Mallinckrodt plc 2016 Form 10-K.

127. Mallinckrodt made thousands of payments to physicians nationwide, including in Ohio, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids

j. Actavis and Associated Companies

128. Defendant Allergan plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland.

129. Defendant Actavis plc acquired Defendant Allergan plc in March 2015; however, the combined company changed its name to Allergan plc in January 2013.

130. Defendant Watson Pharmaceuticals, Inc. had acquired Defendant Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013, and then changed the name to Actavis plc in October 2013.

131. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of Defendant Allergan plc (f/k/a Actavis, Inc., f/k/a, Actavis PLS, f/k/a Watson Pharmaceuticals, Inc.).

132. Defendant Actavis Pharma, Inc. (f/k/a Actavis, Inc., f/k/a Watson Pharma, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc.

133. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

134. Each of these Defendants is owned by Defendant Allergan plc, which uses them to market and sell its drugs in the United States.

135. Defendant Allergan plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. Allergan plc,

Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. (collectively, "Actavis") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States, including to Plaintiffs.

136. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana in the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

137. Actavis made thousands of payments to physicians nationwide including in Ohio, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

138. Collectively, Purdue, Actavis, Amneal, Cephalon, Janssen, Depomed, Endo, Insys, Abbot, and Mallinckrodt are referred to as "Marketing Defendants."

2. Distributor Defendants

139. The Distributor Defendants are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants, who are engaged in "wholesale distribution," universally failed to comply with state law regulating that activity. Plaintiffs allege the unlawful conduct by the Distributor Defendants is a substantial cause for the volume of prescription opioids plaguing Plaintiffs' communities.

a. AmerisourceBergen Drug Corporation

140. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a

wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including to Ohio. AmerisourceBergen is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania.

141. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of \$147 billion in 2016. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania, and it is incorporated in Delaware.

142. According to its 2016 Annual Report, AmerisourceBergen is "one of the largest global pharmaceutical sourcing and distribution services companies, helping both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care."⁴⁴

b. Anda, Inc.

143. Defendant Anda, Inc., ("Anda") through its various DEA registrant subsidiaries and affiliated entities, including but not limited to, Anda Pharmaceuticals, Inc., is the fourth largest distributor of generic pharmaceuticals in the United States. Anda is a Florida corporation with its principal place of business in Weston, Florida. In October 2016, Defendant Teva acquired Anda from Allergan plc (i.e. Defendant Actavis), for \$500 million in cash. At all times relevant to this Complaint, Anda distributed prescription opioids throughout the United States, including in the communities served by Plaintiffs.

c. Cardinal

144. Defendant Cardinal Health, Inc. ("Cardinal") is an Ohio Corporation with its principal place of business in Dublin, Ohio. In 2016, Cardinal generated revenues of \$121.5 billion.

⁴⁴ AmerisourceBergen, 2016 Summary Annual Report,
<http://investor.amerisourcebergen.com/static-files/37daf1ed-4d41-4547-bb87-86d501087dbb>
(last accessed Aug. 1, 2018).

145. Cardinal is a global distributor of pharmaceutical drugs and medical products. It is one of the largest distributors of opioids in the United States. It has annual resources of over \$120 billion. Additionally, in December 2013, Cardinal formed a ten-year agreement with CVS Caremark to form the largest generic drug sourcing operation in the United States. Cardinal has, at all relevant times, had distribution centers throughout the United States, including Ohio, and has distributed opioids nationwide.

d. H. D. Smith, LLC

146. Defendant H. D. Smith, LLC f/k/a H. D. Smith Wholesale Drug Co. ("H. D. Smith") through its various DEA registered subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the United States, including Ohio and the communities served by Plaintiffs. H. D. Smith is a privately held independent pharmaceuticals distributor of wholesale brand, generic and specialty pharmaceuticals and is a Delaware corporation with its principal place of business in Illinois. H. D. Smith, LLC's sole member is H. D. Smith Holdings, LLC, and its sole member is H. D. Smith Holding Company, a Delaware corporation with its principal place of business in Illinois. H. D. Smith is the largest independent wholesaler in the United States. In January 2018, Defendant AmerisourceBergen acquired H. D. Smith.

e. Henry Schein Entities

147. Defendant Henry Schein, Inc. (Henry Schein) describes its business as providing a products and services to integrated health systems, designed specifically for and focused exclusively on, the non-acute care space. Henry Schein is incorporated in Delaware, with its principal place of business located in Melville, New York.

148. Henry Schein distributes, among other things, branded and generic pharmaceuticals to customers that include dental practitioners, dental laboratories, animal health practices and clinics, and office-based medical practitioners, ambulatory surgery centers, and other institutions.

149. At all relevant times, Henry Schein was in the business of distributing, and redistributing, pharmaceutical products to consumers within Ohio.

150. In 2015, Henry Schein reported that its sales reached a record \$10.4 billion and that it had grown at a compound annual rate of approximately 16 percent since becoming a public company in 1995. Overall, it is the world's largest provider of health care products and services to office-based dental, animal health, and medical practitioners.

f. Miami-Luken

151. Defendant Miami-Luken, Inc. ("Miami-Luken") is an Ohio corporation with its headquarters and principal place of business in Springboro, Ohio. At all times relevant to this Complaint, Miami-Luken distributed prescription opioids throughout the United States, including in Ohio.

g. McKesson Corporation

152. McKesson Corporation ("McKesson") is a Delaware corporation with its principal place of business located in San Francisco, California.

153. McKesson is the largest pharmaceutical distributor in North America. McKesson delivers approximately one-third of all pharmaceuticals used in North America, including to Plaintiffs.

154. For fiscal year ended March 31, 2017, McKesson generated revenues of \$198.5 billion.

155. In its 2017 Annual Report, McKesson states that it "partner[s] with pharmaceutical manufacturers, providers, pharmacies, governments and other organizations in healthcare to help

provide the right medicines, medical products and healthcare services to the right patients at the right time, safely and cost-effectively.”⁴⁵

156. According to the 2017 Annual Report, McKesson’s “pharmaceutical distribution business operates and serves thousands of customer locations through a network of 27 distribution centers, as well as a primary redistribution center, two strategic redistribution centers and two repackaging facilities, serving all 50 states and Puerto Rico.”

157. McKesson is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of \$191 billion in 2016. McKesson is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country.

158. In January 2017, McKesson paid a record \$150 million to resolve an investigation by the U.S. Department of Justice (“DOJ”) for failing to report suspicious orders of certain drugs, including opioids. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in Ohio, Florida, Michigan and Colorado. The DOJ described these “staged suspensions” as “among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor.”

159. McKesson is the largest pharmaceutical distributor in the United States.

160. McKesson has more than 40,000 customers nationally.

161. Collectively, McKesson, AmerisourceBergen, and Cardinal account for 85% of the drug shipments in the United States. These companies together collect about \$400 billion in annual revenue.

162. Cardinal, Anda, McKesson, H. D. Smith, Henry Schein, AmerisourceBergen and

⁴⁵ McKesson, Annual Report,
http://investor.mckesson.com/sites/mckesson.investorhq.businesswire.com/files/report/file/2017_McKesson_Annual_Report_0.pdf (last accessed April 12, 2018).

Miami-Luken are collectively referred to as the “Distributor Defendants.”

3. National Retail Pharmacies

a. CVS Health Corporation

163. Defendant CVS Health Corporation (“CVS”) is a Delaware corporation with its principal place of business in Rhode Island. At all times relevant to this Complaint, CVS distributed prescription opioids throughout the United States, including in Ohio.

b. The Kroger Co.

164. Defendant the Kroger Co. (“Kroger”) is an Ohio corporation with headquarters in Cincinnati, OH. Kroger operates 2,268 pharmacies in the United States, including in Ohio. At all times relevant to this Complaint, Kroger distributed prescription opioids throughout the United States, including in Ohio.

c. Rite-Aid of Maryland, Inc.

165. Defendant Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. (“Rite Aid”), is a Maryland corporation with its principal office located in Camp Hill, Pennsylvania. At all times relevant to this Complaint, Rite Aid distributed prescription opioids throughout the United States, including in Ohio.

d. Walgreens Boots Alliance, Inc.

166. Defendant Walgreens Boots Alliance, Inc., also known as Walgreen Co. (“Walgreens”) is a Delaware corporation with its principal place of business in Illinois. At all times relevant to this Complaint, Walgreens distributed prescription opioids throughout the United States, including in Ohio.

e. Wal-Mart Inc.

167. Defendant Wal-Mart Inc., formerly known as Wal-Mart Stores, Inc. (“Wal-Mart”), is a Delaware corporation with its principal place of business in Arkansas. At all times relevant to

this Complaint, Wal-Mart distributed prescription opioids throughout the United States, including in Ohio.

168. Collectively, Defendants CVS, Kroger, Rite Aid, Walgreens, and Wal-Mart are referred to as “National Retail Pharmacies.” Additionally, the Distributor Defendants and the National Retail Pharmacies are collectively referred to as the “Supply Chain Defendants.”

169. Defendants include the above referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the extent that they are engaged in the manufacture, promotion, distribution, and sale and/or dispensing of opioids.

4. Defendants’ Agents and Affiliated Persons

170. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants’ officers, agents, employees, or other representatives while actively engaged in the management of Defendants’ affairs within the course and scope of their duties and employment, and/or with Defendants’ actual, apparent, and/or ostensible authority.

171. The true names and capacities, whether individual, corporate, associate, or otherwise of certain vendors, distributors and/or their alter egos, sued herein as DOES 1 through 100 inclusive, are presently unknown to Plaintiffs, who therefore sue these Defendants by fictitious names. Plaintiffs will seek leave of this Court to amend this Complaint to show their true names and capacities when they become ascertained. Each of the Doe Defendants has taken part in and participated with, and/or aided and abetted, some or all of the other Defendants in some or all of the matters referred to herein, and therefore are liable for the same.

IV. FACTUAL BACKGROUND

A. The History Of Opioids

172. The synthetic opioids manufactured and distributed by Defendants are related to the opium poppy, which has been used to relieve pain for centuries.

173. The opium poppy was a well-known symbol of the Roman Civilization, which signified both sleep and death. The Romans used opium not only as a medicine but also as a poison.⁴⁶

174. During the Civil War, opioids, then known as “tinctures of laudanum,” gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain on the battlefield. They were also used in a wide variety of commercial products ranging from pain elixirs to cough suppressants to beverages.

175. Since 1970, opioids have been regulated under the Controlled Substances Act (“CSA”). Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I the highest. The CSA and state laws impose a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally have been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence; Schedule III drugs are deemed to have a lower potential for abuse, but their abuse may lead to moderate or low physical dependence or high psychological dependence. 21 U.S.C. § 812.

176. The effects of opioids vary by duration. Long-acting opioids, such as Purdue’s OxyContin and MS Contin, Janssen’s Nucynta ER and Duragesic, Endo’s Opana ER, and Actavis’s Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon’s Actiq

⁴⁶ Martin Booth, *Opium: A History*, at 20 (Simon & Schuster Ltd. 1996).

and Fentora, are designed to be taken in addition to long-acting opioids to address “episodic pain” (also referred to as “breakthrough pain”) and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours. Still other short-term opioids, such as Insys’s Subsys, are designed to be taken in addition to long-acting opioids to specifically address breakthrough cancer pain, excruciating pain suffered by some patients with end-stage cancer. The Marketing Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic or “breakthrough” pain.

177. Patients develop tolerance to the analgesic effect of opioids relatively quickly. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same perceived level of pain reduction. The same is true of the euphoric effects of opioids—the “high.” However, opioids depress respiration, and at very high doses can and often do arrest respiration altogether. At higher doses, the effects of withdrawal are more severe. Long-term opioid use can also cause hyperalgesia, a heightened sensitivity to pain.

178. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

179. Opioids provide effective treatment for short-term, post-surgical and trauma-related pain, and for palliative end-of-life care. They are approved by the FDA for use in the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days. Defendants, however, have manufactured, promoted, marketed, and distributed

opioids for the management of chronic pain by misleading consumers and medical providers, such as hospitals, through misrepresentations or omissions regarding the appropriate uses, risks, and safety of opioids.

180. As one doctor put it, the widespread, long-term use of opioids “was an experiment on the population of the United States. It wasn’t randomized, it wasn’t controlled, and no data was collected until they started gathering death statistics.”

B. The Opioid Epidemic

181. Prescription opioids have become widely prescribed. In 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.⁴⁷

182. Despite the enormous number of prescriptions, recent studies have concluded that treatment with opioids is not superior to treatment with non-opioid medications for improving pain-related function.⁴⁸ Even for patients presenting to the emergency room with acute extremity pain, there is no significant or clinically important difference in pain reduction at 2 hours among single-dose treatment with ibuprofen and acetaminophen or with three different opioid and acetaminophen combination analgesics.⁴⁹

⁴⁷ Katherine M. Keyes, et al., *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, 104 Am. J. Pub. Health e52-e59 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3935688/>.

⁴⁸ Erin E. Krebs, M.D., et al., *Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients with Chronic Back Pain or Hip or Knee Osteoarthritis Pain*, 319 JAMA 872-882 (2018), doi: 10.1001/jama.2018.0899, <https://jamanetwork.com/journals/jama/article-abstract/2673971?redirect=true>.

⁴⁹ Andrew K. Chang, M.D., et al., *Effect of a Single Dose of Oral Opioid and Nonopioid Analgesics on Acute Extremity Pain in the Emergency Department*, 318 JAMA 1661-1667 (2017), DOI: 10.1001/jama.2017.16190, <https://jamanetwork.com/journals/jama/article-abstract/2661581?widget=personalizedcontent&previousarticle=2673971&redirect=true>.

183. In 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention, declared prescription painkiller overdoses at epidemic levels. The News Release noted:

- a. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.
- b. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).
- c. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.
- d. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription painkillers non-medically according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.
- e. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.
- f. Almost 5,500 people start to misuse prescription painkillers every day.⁵⁰

184. The CDC has also identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers – which, at the molecular level and in their effect, closely resemble heroin - are forty times more

⁵⁰ See Press Release, Centers for Disease Control and Prevention, Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

likely to be addicted to heroin.⁵¹ According to a recent study, among young urban heroin users, 86% used opioid pain relievers prior to using heroin.⁵²

185. The synthetic opioid fentanyl has been a driving force behind the nation's opioid epidemic, killing tens of thousands of Americans in overdoses. The drug is so powerful that it is now being used to execute prisoners on death row.⁵³

186. In a November 2016 report, the DEA declared opioid prescription drugs, heroin, and fentanyl as the most significant drug-related threats to the United States.⁵⁴

187. The U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999–2014. Among the 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.⁵⁵

188. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.⁵⁶

⁵¹ See Centers for Disease Control and Prevention, *Today's Heroin Epidemic*, <https://www.cdc.gov/vitalsigns/heroin/index.html> (last accessed Aug. 1, 2018).

⁵² Nat'l Inst. on Drug Abuse, *Prescription Opioids and Heroin* (Jan. 2018), <https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/19774-prescription-opioids-and-heroin.pdf>.

⁵³ Smith, Mitch. *Fentanyl Used to Execute Nebraska Inmate, in First for U.S.*, (Aug. 14, 2018), <https://www.nytimes.com/2018/08/14/us/carey-dean-moore-nebraska-execution-fentanyl.html>.

⁵⁴ Rudd, et al., Centers for Disease Control and Prevention, *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015* (Dec. 30, 2016), Morbidity & Mortality Wkly. Rep. 2016; 65; 1445-1452, doi: <http://dx.doi.org/10.15585/mmwr.mm655051e1>, available at <https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm>.

⁵⁵ See Rudd, et al., Centers for Disease Control and Prevention, *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015* (Dec. 30, 2016), Morbidity & Mortality Wkly. Rep. 2016; 65; 1445-1452, DOI: <http://dx.doi.org/10.15585/mmwr.mm655051e1>, available at <https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm>.

⁵⁶ See Nora D. Volkow, M.D. & A. Thomas McLellan, M.D., *Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies*, 374 N Engl J Med 1253-1263 (2016), DOI: 10.1056/NEJMra1507771, <http://www.nejm.org/doi/full/10.1056/NEJMra1507771>, (hereinafter “Volkow & McLellan”).

189. The National Institute on Drug Abuse identifies misuse and addiction to opioids as “a serious national crisis that affects public health as well as social and economic welfare.”⁵⁷ The economic burden of prescription opioid misuse alone is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.⁵⁸

190. In 2017, the President of the United States officially declared an opioid and heroin epidemic.⁵⁹

C. Congressional Response to the Opioid Crisis

191. Congressional interest in the opioid crisis has been intense. Multiple committees in both the House and Senate have conducted dozens of hearings exploring the issue from almost every angle, including effects on the health care system, people and their communities, law enforcement, workplaces, schools, and the Native American community. Congressional efforts culminated in the passage of the “Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act,” or the “SUPPORT for Patients and Communities Act.” This Bill passed the House by a vote of 396-14 on June 22, 2018, passed the Senate by a vote of 99-1 on September 17, 2018, and was signed into law by the President on October 24, 2018. Among other provisions, the Bill made it easier to intercept drugs being shipped into the country, authorized new funding for more comprehensive treatment, sped up research on non-addictive painkillers, and provided for broader coverage for substance abuse under Medicare

⁵⁷ *Id.*

⁵⁸ *Id.* (citing at note 2, Florence CS, et al., *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013* (Oct. 2016), 54 Med. Care 901-906 (2016), DOI: 10.1097/MLR.0000000000000625, available at <https://www.ncbi.nlm.nih.gov/pubmed/27623005>).

⁵⁹ See Proclamation No. 9499, 81 Fed. Reg. 65173 (Sept. 16, 2016) (proclaiming “Prescription Opioid and Heroin Epidemic Awareness Week”), available at <https://www.gpo.gov/fdsys/pkg/FR-2016-09-22/pdf/2016-22960.pdf>.

and Medicaid regulations that have occasionally stood in the way of treatment. Congressional interest in the issue is ongoing.

V. THE MARKETING DEFENDANTS' FALSE, DECEPTIVE, AND UNFAIR MARKETING OF OPIOIDS

192. The opioid epidemic did not happen by accident.

193. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

194. Each Marketing Defendant has conducted, and continues to conduct, a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Marketing Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny, trivialize, or materially underestimate the risks of opioids while overstating the benefits of using them for chronic pain.

195. The Marketing Defendants have disseminated these common messages to reverse the generally accepted medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians that the Marketing Defendants recruited for their support of their marketing messages, and through unbranded marketing and industry-funded Front Groups.

196. The Marketing Defendants' efforts have been wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated \$11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded \$8 billion in revenue annually since 2009.⁶⁰ In an open letter to the nation's physicians in August 2016, the then U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors ... [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."⁶¹ This epidemic has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to buy prescription opioids or even non-prescription opioids, like heroin.

197. The Marketing Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

198. As alleged throughout this Complaint, Defendants' conduct created a public health crisis and a public nuisance.

199. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm can be abated by, *inter alia*, (a) educating prescribers (especially primary care physicians and the most prolific prescribers of opioids) and patients regarding the true risks and benefits of opioids, including the risk of addiction, in order to prevent the next cycle of addiction; (b) providing addiction treatment

⁶⁰ See Katherine Eban, *Oxycontin: Purdue Pharma's Painful Medicine*, FORTUNE (Nov. 9, 2011), <http://fortune.com/2011/11/09/oxycontin-purdue-pharma-s-painful-medicine/>; David Crow, *Drugmakers Hooked on \$10bn Opioid Habit*, FINANCIAL TIMES (Aug. 10, 2016).

⁶¹ Letter from Vivek H. Murthy, M.D., U.S. Surgeon General.

to patients who are already addicted to opioids; and (c) making naloxone widely available so that overdoses are less frequently fatal.

200. Defendants have the ability to act to abate the public nuisance, and the law recognizes that they must do so. It is the manufacturer of a drug that has primary responsibility to ensure the safety, efficacy, and appropriateness of a drug's labeling, marketing, and promotion. All companies in the supply chain of a controlled substance are primarily responsible for ensuring that such drugs are only distributed and dispensed to appropriate patients and not diverted. These responsibilities, to ensure that their products and practices meet both federal and state consumer protection laws and regulations, exist independent of any FDA or DEA regulation. As registered manufacturers and distributors of controlled substances, Defendants are placed in a position of special trust and responsibility, and are uniquely positioned, based on their knowledge of prescribers and orders, to act as a first line of defense.

A. The Marketing Defendants' False and Deceptive Statements About Opioids

201. The Marketing Defendants' misrepresentations fall into the following ten categories:

1. The risk of addiction from chronic opioid therapy is low;
2. To the extent there is a risk of addiction, it can be easily identified and managed;
3. Signs of addictive behavior are "pseudoaddiction," requiring more opioids;
4. Blaming addicts as "abusers" of opioids;
5. Opioid withdrawal can be avoided by tapering;
6. Opioid doses can be increased without limit or greater risks;
7. Long-term opioid use improves functioning;
8. Alternative forms of pain relief pose greater risks than opioids;

9. A version of OxyContin marketed by Purdue was effective in providing 12-hour pain relief; and
 10. New formulations of certain opioids successfully deter abuse.
202. Each of these propositions was false. The Marketing Defendants knew this, but they nonetheless set out to convince physicians, patients, and the public at large of the truth of each of these propositions in order to expand the market for their opioids.
203. The categories of misrepresentations are offered to organize the numerous statements the Marketing Defendants made and to explain their role in the overall marketing effort, not as a checklist for assessing each Marketing Defendant's liability. While each Marketing Defendant deceptively promoted their opioids specifically, and, together with other Marketing Defendants, opioids generally, not every Marketing Defendant propagated (or needed to propagate) each misrepresentation. Each Marketing Defendant's conduct, and each misrepresentation, contributed to an overall narrative that aimed to—and did—mislead doctors, patients, and payors about the risks and benefits of opioids. While this Complaint endeavors to document examples of each Marketing Defendant's misrepresentations and the manner in which they were disseminated, they are just that—examples. The Complaint is not, especially prior to discovery, an exhaustive catalog of the nature and manner of each deceptive statement by each Marketing Defendant.

- 1. Falsehood #1: The Risk of Addiction from Chronic Opioid Therapy is Low**

204. Central to the Marketing Defendants' promotional scheme was the misrepresentation that opioids are rarely addictive when taken for chronic pain. Through their marketing efforts, the Marketing Defendants advanced the idea that the risk of addiction is low when opioids are taken as prescribed by "legitimate" pain patients. That, in turn, directly led to the

expected and intended result that doctors prescribed more opioids to more patients—thereby enriching the Marketing Defendants and substantially contributing to the opioid epidemic.

205. Each of the Marketing Defendants claimed that the potential for addiction from its opioids was relatively small or non-existent, even though there was no scientific evidence to support those claims. None of them have acknowledged, retracted, or corrected their false statements.

206. In fact, studies have shown that a substantial percentage of long-term users of opioids experience addiction. Addiction can result from the use of any opioid, “even at recommended dose,”⁶² and the risk substantially increases with more than three months of use.⁶³ As the CDC Guideline states, “[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder” (a diagnostic term for addiction).⁶⁴

a. Purdue and Abbott’s Misrepresentations Regarding Addiction Risk

207. When it launched OxyContin, Purdue knew it would need data to overcome decades of wariness regarding opioid use. It needed some sort of research to back up its messaging. But, Purdue had not conducted any studies about abuse potential or addiction risk as part of its application for FDA approval for OxyContin. Purdue (and, later, the other Defendants) found this “research” in the form of a one-paragraph letter to the editor published in the New England Journal of Medicine (“NEJM”) in 1980.

⁶² FDA announces safety labeling changes and post market study requirements for extended-release and long-acting opioid analgesics, FDA (Sept. 10, 2013); *see also* FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death, FDA (Mar. 22, 2016).

⁶³ CDC Guideline at 21.

⁶⁴ *Id.* at 2.

208. This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of addiction “rare” for patients treated with opioids.⁶⁵ They had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. Porter and Jick considered a patient not addicted if there was no sign of addiction noted in patients’ records.

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients¹ who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,² Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. *JAMA*. 1970; 213:1455-60.
 2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. *J Clin Pharmacol*. 1978; 18:180-8.

209. As Dr. Jick explained to a journalist years later, he submitted the statistics to NEJM as a letter because the data were not robust enough to be published as a study.⁶⁶

210. Purdue nonetheless began repeatedly citing this letter in promotional and educational materials as evidence of the low risk of addiction, while failing to disclose that its source was a letter to the editor, not a peer-reviewed paper.⁶⁷ Citation of the letter, which was largely ignored for more than a decade, significantly increased after the introduction of OxyContin.

⁶⁵ Jane Porter & Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) N Engl J Med. 123 (Jan. 10, 1980),
<http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221>.

⁶⁶ Meier, *Pain Killer*, at 174.

⁶⁷ J. Porter & H. Jick, Addiction Rare in Patients Treated with Narcotics, 302(2) New. Eng. J. Med. 123 (1980).

While first Purdue and then other Marketing Defendants used it to assert that their opioids were not addictive, “that’s not in any shape or form what we suggested in our letter,” according to Dr. Jick.

211. Purdue specifically used the Porter and Jick letter in its 1998 promotional video “I got my life back,” in which Dr. Alan Spanos states “In fact, the rate of addiction amongst pain patients who are treated by doctors *is much less than 1%*.⁶⁸ Purdue trained its sales representatives to tell prescribers that less than 1% of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was 13%).⁶⁹

212. Other Defendants relied on and disseminated the same false and deceptive messaging. The enormous impact of Defendants’ misleading amplification of this letter was well documented in another letter published in the NEJM on June 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and, in some cases, “grossly misrepresented.” In particular, the authors of this letter explained:

[W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers’ concerns about the risk of addiction associated with long-term opioid therapy.⁷⁰

⁶⁸ Our Amazing World, *Purdue Pharma OxyContin Commercial*, <https://www.youtube.com/watch?v=Er78Dj5hyeI>, (last accessed Aug. 1, 2018) (emphasis added).

⁶⁹ Keefe, *Empire of Pain*.

⁷⁰ Leung, et al., *A 1980 Letter on the Risk of Opioid Addiction*, 376 N Engl. J Med 2194-95 (June 1, 2017), <http://www.nejm.org/doi/full/10.1056/NEJMc1700150#t=article>.

213. “It’s difficult to overstate the role of this letter,” said Dr. David Juurlink of the University of Toronto, who led the analysis. “It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern.”⁷¹

214. Alongside its use of the Porter and Jick letter, Purdue also crafted its own materials and spread its deceptive message through numerous additional channels. In its 1996 press release announcing the release of OxyContin, for example, Purdue declared, “The fear of addiction is exaggerated.”⁷²

215. Abbott sales staff were instructed about the euphoria patients were receiving on the shorter-acting painkiller Vicodin, they should tell the physician that “OxyContin has fewer such effects.” Abbott’s “King of Pain” taught his staff of “Royal Crusaders” that OxyContin would “minimize[e] the risk of dependence” and “lower[] euphoria,” when, in fact, he had little knowledge of pharmacology and no basis for these statements.

216. At a hearing before the House of Representatives’ Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Purdue emphasized “legitimate” treatment, dismissing cases of overdose and death as something that would not befall “legitimate” patients: “Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional.”⁷³

⁷¹ *Painful words: How a 1980 letter fueled the opioid epidemic*, STAT (May 31, 2017), <https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter/>.

⁷² Press Release, OxyContin, *New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain* (May 31, 1996), <http://documents.latimes.com/oxycontin-press-release-1996/>.

⁷³ *Oxycontin: Its Use and Abuse: Hearing Before the H. Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 107th Cong. 1 (Aug. 28, 2001) (statement of Michael Friedman, Executive Vice President, Chief Operating Officer, Purdue Pharma, L.P.), <https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/html/CHRG-107hhrg75754.htm>.

217. Purdue spun this baseless “legitimate use” distinction out even further in a patient brochure about OxyContin, called *A Guide to Your New Pain Medicine and How to Become a Partner Against Pain*. In response to the question “Aren’t opioid pain medications like OxyContin Tablets ‘addicting?’” Purdue claimed that there was no need to worry about addiction if taking opioids for legitimate, “medical” purposes: “Drug addiction means using a drug to get “high” rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.”

218. Sales representatives marketed OxyContin as a product “to start with and to stay with.”⁷⁴ Sales representatives also received training in overcoming doctors’ concerns about addiction with talking points they knew to be untrue about the drug’s abuse potential. One of Purdue’s early training memos compared doctor visits to “firing at a target,” declaring that “[a]s you prepare to fire your ‘message,’ you need to know where to aim and what you want to hit!”⁷⁵ According to the memo, the target is physician resistance based on concern about addiction: “The physician wants pain relief for these patients without addicting them to an opioid.”⁷⁶

219. Purdue, through its unbranded website *Partners Against Pain*,⁷⁷ stated the following: “Current Myth: Opioid addiction (psychological dependence) is an important clinical

⁷⁴ Keefe, *Empire of Pain*.

⁷⁵ *Pain Killer*, at 102.

⁷⁶ *Id.*

⁷⁷ *Partners Against Pain* consists of both a website, styled as an “advocacy community” for better pain care, and a set of medical education resources distributed to prescribers by sales representatives. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin’s addictiveness by claiming: “Drug addiction means using a drug to get ‘high’ rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.”

problem in patients with moderate to severe pain treated with opioids. Fact: Fears about psychological dependence are exaggerated when treating appropriate pain patients with opioids.”

220. Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist how he and his coworkers were trained to overcome doctors’ objections to prescribing opioids. The most common objection he heard about prescribing OxyContin was that “it’s just too addictive.”⁷⁸ May and his coworkers were trained to “refocus” doctors on “legitimate” pain patients, and to represent that “legitimate” patients would not become addicted. In addition, they were trained to say that the 12-hour dosing made the extended-release opioids less “habit-forming” than painkillers that need to be taken every four hours.

221. According to interviews with prescribers and former Purdue sales representatives, Purdue has continued to distort or omit the risk of addiction while failing to correct its earlier misrepresentations, leaving many doctors with the false impression that pain patients will only rarely become addicted to opioids.

222. With regard to addiction, Purdue’s label for OxyContin has not sufficiently disclosed the true risks to, and experience of, its patients. Until 2014, the OxyContin label stated in a black-box warning that opioids have “abuse potential” and that the “risk of abuse is increased in patients with a personal or family history of substance abuse.”

223. However, the FDA made clear to Purdue as early as 2001 that the disclosures in its OxyContin label were insufficient.

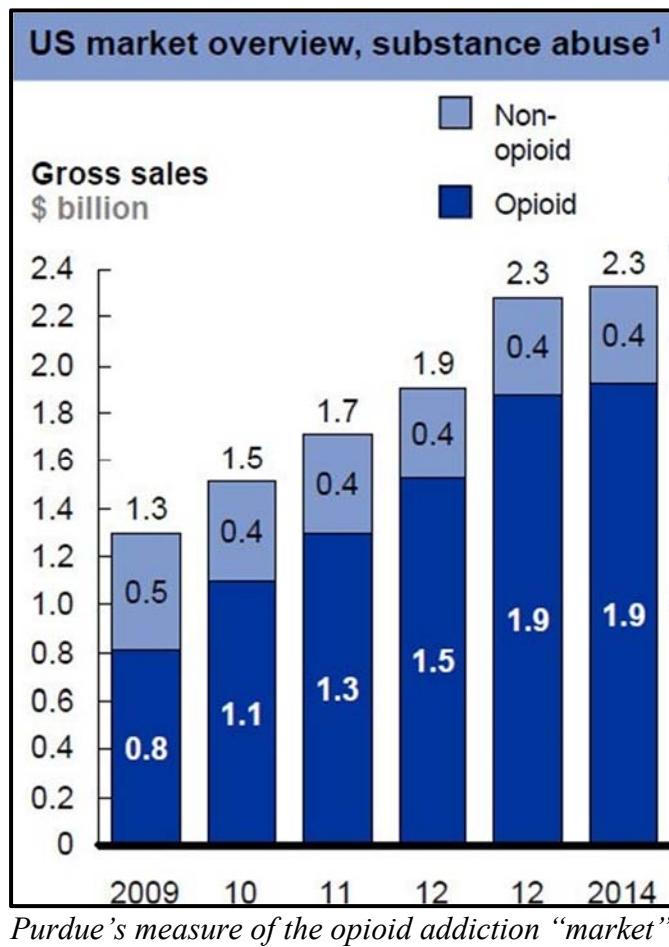
224. In 2001, Purdue revised the indication and warnings for OxyContin.

225. In the end, Purdue narrowed the recommended use of OxyContin to situations

⁷⁸ David Remnick, *How OxyContin Was Sold to the Masses* (Steven May interview with Patrick Radden Keefe), The New Yorker (Oct. 27, 2017), <https://www.newyorker.com/podcast/the-new-yorker-radio-hour/how-oxycontin-was-sold-to-the-masses>.

when “a continuous, around-the-clock analgesic is needed for an extended period of time” and added a warning that “[t]aking broken, chewed, or crushed OxyContin tablets” could lead to a “potentially fatal dose.” However, Purdue did not, until 2014, change the label to indicate that OxyContin should not be the first therapy, or even the first opioid, used, and did not disclose the incidence or risk of overdose and death even when OxyContin was not abused. Purdue announced the label changes in a letter to health care providers.

226. The Purdue Defendants’ awareness of the addictive properties of their opioid products is best exemplified by their cynical attempts to profit from addiction treatment. In 2007, Defendant Richard Sackler filed an application for a patent for a purported treatment for opioid addiction. In September 2014, Defendant Kathe Sackler dialed in to a confidential call about *Project Tango* -- a secret plan for Purdue to expand into the business of selling drugs to treat opioid addiction. In their internal documents, Kathe and staff wrote down what Purdue publicly denied for decades: that addictive opioids and opioid addiction are “naturally linked.” They determined that Purdue should expand across “the pain and addiction spectrum,” to become “an end-to-end pain provider.” Purdue illustrated the end-to-end business model with a picture of a dark hole labeled “Pain treatment” that a patient could fall into — and “Opioid addiction treatment” waiting at the bottom. Kathe Sackler and the *Project Tango* team reviewed their findings that the “market” of people addicted to opioids, measured coldly in billions of dollars, had doubled from 2009 to 2014:



227. Kathe and the staff found that the catastrophe provided an excellent compound annual growth rate (“CAGR”): “Opioid addiction (other than heroin) has grown by ~20% CAGR from 2000 to 2010.” Kathe Sackler and the staff revealed in their internal documents that Purdue’s tactic of blaming addiction on untrustworthy patients was a lie. Instead, the truth is that opioid addiction can happen to anyone who is prescribed opioids:

- *“This can happen to any-one – from a 50 year old woman with chronic lower back pain to a 18 year old boy with a sports injury, from the very wealthy to the very poor”*

Purdue’s “Project Tango” patient and clinical rationale

Kathe and the staff concluded that millions of people who became addicted to opioids were the Sackler Defendants' next business opportunity. Staff wrote: "It is an attractive market. Large unmet need for vulnerable, underserved and stigmatized patient population suffering from substance abuse, dependence and addiction." The team identified eight ways that Purdue's experience getting patients *on* opioids could now be used to sell treatment for opioid addiction.

228. In June 2017, the Sackler Defendants met to discuss a revised version of *Project Tango* - another try at profiting from the opioid crisis. This time, they considered a scheme to sell the overdose antidote NARCAN. The need for NARCAN to reverse overdoses was rising so fast that the Sacklers calculated it could provide a growing source of revenue, tripling from 2016 to 2018.

b. Endo's Misrepresentations Regarding Addiction Risk

229. Endo also falsely represented that addiction is rare in patients who are prescribed opioids.

230. Until April 2012, Endo's website for Opana, www.opana.com, stated that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."

231. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that Endo improperly instructed its sales representatives to diminish and distort the risk of addiction associated with Opana ER.

232. One of the Front Groups with which Endo worked most closely was the American Pain Foundation ("APF"), described more fully below.

233. APF conveyed through its National Initiative on Pain Control ("NIPC") and its website www.Painknowledge.com, which claimed that "[p]eople who take opioids as prescribed usually do not become addicted."

234. Another Endo website, www.PainAction.com, stated: “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.”

235. A brochure available on www.Painknowledge.com titled “*Pain: Opioid Facts*,” an Endo- sponsored NIPC, stated that “people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted.” In numerous patient education pamphlets, Endo repeated this deceptive message.

236. In a patient education pamphlet titled “*Understanding Your Pain: Taking Oral Opioid Analgesics*,” Endo answers the hypothetical patient question—“What should I know about opioids and addiction?”—by focusing on explaining what addiction is (“a chronic brain disease”) and is not (“Taking opioids for pain relief”). It goes on to explain that “[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction.” This publication is still available online and was edited by KOL Dr. Russell Portenoy.⁷⁹

237. In addition, a 2009 patient education publication, *Pain: Opioid Therapy*, funded by Endo and posted on www.Painknowledge.com, omitted addiction from the “common risks” of opioids, as shown below:

⁷⁹ Margo McCaffery, RN MS, FAAN and Chris Pasero, RN, MS FAAN, *Understanding Your Pain, Taking Oral Opioid Analgesics*, available at http://www.thblack.com/links/rsd/understand_pain_opioid_analgesics.pdf (last accessed October 26, 2018).

As with any medication, there are some side effects that are associated with opioid therapy. The most common side effects that occur with opioid use include the following:

- ▶ Constipation
- ▶ Drowsiness
- ▶ Confusion
- ▶ Nausea
- ▶ Itching
- ▶ Dizziness
- ▶ Shortness of breath

Your healthcare provider can help to address and, in some cases, prevent side effects that may occur as a result of opioid treatment. Less severe side effects, including nausea, itching, or drowsiness, typically go away within a few days without the need for further treatment. If you experience any side effects, you should let your healthcare provider know immediately.

c. Janssen's Misrepresentations Regarding Addiction Risk

238. Janssen likewise misrepresented the addiction risk of opioids on its websites and print materials. One website, *Let's Talk Pain*, states, among other things, that “the stigma of drug addiction and abuse” associated with the use of opioids stemmed from a “lack of understanding addiction.”

239. The *Let's Talk Pain* website also perpetuated the concept of pseudoaddiction, associating patient behaviors such as “drug seeking,” “clock watching,” and “even illicit drug use or deception” with undertreated pain which can be resolved with “effective pain management.”

240. A Janssen unbranded website, www.PrescribeResponsibly.com, states that concerns about opioid addiction are “overestimated” and that “true addiction occurs only in a small percentage of patients.”⁸⁰

241. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults*, which, as seen below, described as

⁸⁰ Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, <http://www.prescriberesponsibly.com/articles/opioid-pain-management> (last modified July 2, 2015).

“myth” that opioids are addictive, and asserted as fact that “[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain” (emphasis in original). Until recently, this guide was still available online.

Opioid myths

Myth: Opioid medications are always addictive.

Fact: Many studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.

242. Janssen’s website for Duragesic included a section addressing “Your Right to Pain Relief” and a hypothetical patient’s fear that “I’m afraid I’ll become a drug addict.” The website’s response: “Addiction is relatively rare when patients take opioids appropriately.”

d. Cephalon’s Misrepresentations Regarding Addiction Risk

243. Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient’s Guide*, which included claims that “patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids.” Similarly, Cephalon sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

244. For example, a 2003 Cephalon-sponsored CME presentation titled *Pharmacologic Management of Breakthrough or Incident Pain*, posted on Medscape in February 2003, teaches:

[C]hronic pain is often undertreated, particularly in the non-cancer patient population. ... The continued stigmatization of opioids and their prescription,

coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to under treatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.⁸¹

e. Mallinckrodt's Misrepresentations Regarding Addiction Risk

245. As described below, Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR, and opioids generally, in a campaign that consistently mischaracterized the risk of addiction. Mallinckrodt did so through its website and sales force, as well as through unbranded communications distributed through the “C.A.R.E.S. Alliance” it created and led.

246. Mallinckrodt in 2010 created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as “a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits.” The “C.A.R.E.S. Alliance” itself is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.) copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

247. By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book titled *Defeat Chronic Pain Now!* This book is still available online.⁸² The false claims and

⁸¹ Michael J. Brennan, et al., Pharmacologic Management of Breakthrough or Incident Pain, Medscape, <http://www.medscape.org/viewarticle/449803>, (last accessed July 27, 2017).

⁸² Available at, https://books.google.com/books?id=VcSQGYKXWdYC&printsec=frontcover&source=gbs_Vie wAPI#v=snippet&q=only%20rarely%20does%20opioid%20medication&f=false

misrepresentations in this book include the following statements:

- a. "Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
- b. "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."
- c. "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."
- d. "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."
- e. "**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
- f. "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."
- g. "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

248. In a 2013 *Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain and Control of Opioid Abuse*, which is still available online, Mallinckrodt stated that, "[s]adly, even today, pain frequently remains undiagnosed and either untreated or undertreated" and cites to a report that concludes that "the majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others."

249. Marketing Defendants' suggestions that the opioid epidemic is the result of bad patients who manipulate doctors to obtain opioids illicitly helped further their marketing scheme is at odds with the facts. While there are certainly patients who unlawfully obtain opioids, they are a small minority. For example, patients who "doctor-shop"—i.e., visit multiple prescribers to

obtain opioid prescriptions—are responsible for roughly 2% of opioid prescriptions. The epidemic of opioid addiction and abuse is overwhelmingly a problem of false marketing (and unconstrained distribution) of the drugs, not problem patients.

2. Falsehood #2: To the Extent There is a Risk of Addiction, It Can Be Easily Identified and Managed

250. While continuing to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted, the Marketing Defendants assert that to the extent that *some* patients are at risk of opioid addiction, doctors can effectively identify and manage that risk by using screening tools or questionnaires. In materials they produced, sponsored, or controlled, Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting opioid therapy for chronic pain. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance use, mental illness, trauma, or abuse) so that doctors can then more closely monitor those patients.

251. Purdue shared its *Partners Against Pain* “Pain Management Kit,” which contains several screening tools and catalogues of Purdue materials.

252. Janssen, on its website www.PrescribeResponsibly.com, states that the risk of opioid addiction “can usually be managed” through tools such as opioid agreements between patients and doctors.⁸³ The website, which directly provides screening tools to prescribers for risk

⁸³ Howard A. Heit, MD, FACP, FASAM & Douglas L. Gourlay, MD, MSc, FRCPC, FASAM, *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, <http://www.prescriberesponsibly.com/articles/before-prescribing-opioids#pseudoaddiction>, (last modified July 2, 2015).

assessments,⁸⁴ includes a “[f]our question screener” to purportedly help physicians identify and address possible opioid misuse.⁸⁵

253. Purdue and Cephalon sponsored the APP’s *Treatment Options: A Guide for People Living with Pain* (2007), which also falsely reassured patients that opioid agreements between doctors and patients can “ensure that you take the opioid as prescribed” and counseled patients that opioids “give [pain patients] a quality of life we deserve.”

254. Purdue sponsored a 2011 webinar taught by Dr. Lynn Webster, entitled *Managing Patient’s Opioid Use: Balancing the Need and Risk*. This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing “overuse of prescriptions” and “overdose deaths.”

255. Purdue sponsored a 2011 CME program titled *Managing Patient’s Opioid Use: Balancing the Need and Risk*. This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented “overuse of prescriptions” and “overdose deaths.”

256. Purdue also funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, even high-risk patients showing signs of addiction could be treated with opioids.

257. Endo paid for a 2007 supplement available for continuing education credit in the *Journal of Family Practice* written by a doctor who became a member of Endo’s speaker’s bureau in 2010. This publication, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*,

⁸⁴ Risk Assessment Resources, <http://www.prescriberesponsibly.com/risk-assessment-resources> (last accessed Feb. 15, 2019).

⁸⁵ *Id.*

(i) recommended screening patients using tools like (a) the *Opioid Risk Tool* (ORT) created by Dr. Webster and linked to Janssen or (b) the *Screener and Opioid Assessment for Patients with Pain*, and (ii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a “maximally structured approach” involving toxicology screens and pill counts. The ORT was linked to Endo-supported websites, as well.

258. There are three fundamental flaws in the Marketing Defendants’ representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that doctors can depend on the screening tools currently available to materially limit the risk of addiction. Second, there is no reliable scientific evidence that high-risk patients identified through screening can take opioids long-term without triggering addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients who are not identified through such screening can take opioids long-term without significant danger of addiction.

3. Falsehood #3: Signs of Addictive Behavior are “Pseudoaddiction” Requiring More Opioids

259. The Marketing Defendants instructed patients and prescribers that signs of addiction are actually indications of untreated pain, such that the appropriate response is to prescribe even more opioids. Dr. David Haddox, who later became a Senior Medical Director for Purdue, published a study in 1989 coining the term “pseudoaddiction,” which he characterized as “the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management.”⁸⁶ In other words, people on prescription opioids who exhibited classic signs of addiction—for example, asking for more and higher doses of opioids, self-escalating their doses,

⁸⁶ David E. Weissman & J. David Haddox, *Opioid pseudoaddiction—an iatrogenic syndrome*, 36(3) Pain 363-66 (Mar. 1989), <https://www.ncbi.nlm.nih.gov/pubmed/2710565>. (“Iatrogenic” describes a condition induced by medical treatment.)

or claiming to have lost prescriptions in order to get more opioids—were not addicted, but rather simply suffering from under-treatment of their pain.

260. In the materials and outreach they produced, sponsored, or controlled, the Marketing Defendants made each of these misrepresentations and omissions, and have never acknowledged, retracted, or corrected them.

261. Cephalon, Endo, and Purdue sponsored the Federation of State Medical Boards' ("FSMB") *Responsible Opioid Prescribing* (2007) written by Dr. Scott Fishman and discussed in more detail below, which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, which are signs of genuine addiction, are all really signs of "pseudoaddiction."

262. Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on its unbranded website, www.PartnersAgainstPain.com, in 2005, and circulated this pamphlet through at least 2007 and on its website through at least 2013. The pamphlet listed conduct including "illicit drug use and deception" that it claimed was not evidence of true addiction but "pseudoaddiction" caused by untreated pain:

"A term which has been used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may 'clock watch,' and may otherwise seem inappropriately 'drug-seeking.' Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated.

Purdue again urged doctors to prescribe higher doses, stating that opioids "are frequently underdosed - or even withheld due to a widespread lack of information ... about their use among healthcare professionals.

263. According to documents provided by a former Purdue detailer, sales representatives were trained and tested on the meaning of pseudoaddiction, from which it can be inferred that sales

representatives were directed to, and did, describe pseudoaddiction to prescribers. Purdue's *Pain Management Kit* is another example of publication used by Purdue's sales force that endorses pseudoaddiction by claiming, "pain-relief seeking behavior can be mistaken for drug-seeking behavior." In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that the kit was in use from roughly 2011 through at least June 2016.

264. A Purdue presentation for doctors titled *Medication Therapy Management* recited what had been the consensus view for decades: "Many medical students are taught that if opioids are prescribed in high doses or for a prolonged time, the patient will become an addict." Purdue then assured doctors that this traditional concern about addiction was wrong — that patients instead suffer from "pseudoaddiction" because "opioids are frequently prescribed in doses that are inadequate." Doctors on Purdue's payroll admitted in writing that pseudoaddiction was used to describe "behaviors that are clearly characterized as drug abuse" and put Purdue at risk of "ignoring" addiction and "sanctioning abuse." Purdue, nevertheless, urged doctors to respond to signs of addiction by prescribing higher doses of Purdue's drugs.

265. Purdue publications touting the concept of "pseudoaddiction" were regularly provided to the Purdue Individual Defendants by Purdue staff. Staff also regularly reported on the distribution of such materials to the Purdue Individual Defendants.

266. Endo also sponsored a NIPC CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction and listed "[d]ifferentiation among states of physical dependence, tolerance, pseudoaddiction, and addiction" as an element to be considered in awarding grants to CME providers.

267. Endo itself has repudiated the concept of pseudoaddiction. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by

some of its proponents,” the New York Attorney General, in a 2016 settlement with Endo, reported that “Endo’s Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the ‘pseudoaddiction’ concept” and acknowledged the difficulty in distinguishing “between addiction and ‘pseudoaddiction.’”⁸⁷ Endo thereafter agreed not to “use the term ‘pseudoaddiction’ in any training or marketing” in New York.

268. The FAQs section of www.pain-topics.org, a now-defunct website to which Mallinckrodt provided funding, also contained misleading information about pseudoaddiction. Specifically, the website advised providers to “keep in mind” that signs of potential drug diversion, rather than signaling “actual” addiction, “may represent pseudoaddiction,” which the website described as behavior that occurs in patients when pain is “undertreated” and includes patients becoming “very focused on obtaining opioid medications and may be erroneously perceived as ‘drug seeking.’”

269. Janssen sponsored, funded, and edited a website called *Let’s Talk Pain*, which in 2009 stated “pseudoaddiction . . . refers to patient behaviors that may occur when pain is undertreated. . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management.” This website was accessible online until at least May 2012. Janssen also currently runs a website, www.Prescriberesponsibly.com, which claims that concerns about opioid addiction are “overestimated,” and describes pseudoaddiction as “a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy

⁸⁷ Attorney General of the State of New York, In the Matter of Endo Health Solutions Inc. & Endo Pharmaceuticals Inc., Assurance No.:15-228, Assurance of Discontinuance Under Executive Law Section 63. Subdivision 15 at 7.

being prescribed. Typically, when the pain is treated appropriately the inappropriate behavior ceases.”⁸⁸

270. The CDC Guidelines nowhere recommend attempting to provide more opioids to patients exhibiting symptoms of addiction. Dr. Lynn Webster, a KOL discussed below, admitted that pseudoaddiction “is already something we are debunking as a concept” and became “too much of an excuse to give patients more medication. It led us down a path that caused harm.”

4. Falsehood #4: Blaming Addicted Patients as “Untrustworthy” “Abusers”

271. A recurring strategy employed by the Purdue Defendants, over a period of decades, was to blame any negative consequences from opioid use on moral failings of a minority of users, who would be labeled as “abusers” or “untrustworthy” people.

272. In 2001, Defendant Richard Sackler wrote down his solution to the overwhelming evidence of overdose and death: blame and stigmatize people who become addicted to opioids. Sackler wrote in a confidential email: “we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals.” The Sackler Defendants chose to stigmatize people who were hurt by opioids, calling them “junkies” and “criminals.”

273. In December 2011, Defendant John Stewart gave a speech titled *Providing Relief, Preventing Abuse* in Connecticut, which deceptively blamed the addiction, overdose, and death on “abuse.” A Purdue pamphlet entitled “*Responsible Opioid Prescribing*” told doctors that only “a small minority of people seeking treatment may not be reliable or trustworthy” and not suitable for addictive opioid drugs.

⁸⁸ Howard Heit, MD, FACP, FASAM, & Douglas Gourlay, MD, MSc, FRCPC, FASAM, *What a Prescriber Should Know Before Writing the First Prescription, Prescribe Responsibly*, <http://www.prescriberesponsibly.com/articles/before-prescribing-opioids>, (last accessed July 16, 2018).

274. Purdue managers praised sales representatives for pitching doctors on the idea that prescribing to “trustworthy” patients was safe. A sales rep reported that one doctor: “let me know that she will Rx OxyContin when the pts [patients] has chronic pain and are trustworthy.” The rep added that he would “Follow up with Dr and ask what pts does she consider ‘trust worthy?’” A Purdue district manager responded: “Great follow up question on what patients does he consider trustworthy.”

275. Defendant Richard Sackler, in a 2007 patent application he filed for a purported treatment for opioid addiction, referred to addicts as “junkies.” In the application, he asks for a monopoly on the treatment of addicts. He received the patent in January 2018.

5. Falsehood #5: Opioid Withdrawal Can Be Avoided by Tapering

276. In an effort to underplay the risk and impact of addiction, the Marketing Defendants falsely claimed that, while patients become physically dependent on opioids, physical dependence is not the same as addiction and can be easily addressed, if and when pain relief is no longer desired, by gradually tapering a patient’s dose to avoid the adverse effects of withdrawal. Defendants failed to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—adverse effects that also make it less likely that patients will be able to stop using the drugs. Defendants also failed to disclose how difficult it is for patients to stop using opioids after they have used them for a prolonged period.

277. A non-credit educational program sponsored by Endo, *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient’s opioid dose over ten days.

278. However, this claim is at odds with the experience of patients addicted to opioids. Most patients who have been taking opioids regularly will, upon stopping treatment, experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea,

headaches, and delirium, among others. This painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

279. Purdue sponsored APP's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but the guide did not disclose the significant hardships that often accompany cessation of use.

280. To this day, the Marketing Defendants have not corrected or retracted their misrepresentations regarding tapering as a solution to opioid withdrawal.

6. Falsehood #6: Opioid Doses Can Be Increased Without Limit or Greater Risk

281. In materials they produced, sponsored, or controlled, Marketing Defendants instructed prescribers that they could safely increase a patient's dose to achieve pain relief. Each of the Marketing Defendants' claims was deceptive in that they omitted warnings of increased adverse effects that occur at higher doses that were confirmed by scientific evidence.

282. These misrepresentations were integral to the Marketing Defendants' promotion of prescription opioids. As discussed above, patients develop a tolerance to opioids' analgesic effects, so that achieving long-term pain relief requires constantly increasing the dose. Patients who take larger doses, and who escalate to larger doses faster, are much more likely to remain on opioids for a longer period of time, resulting in increased revenue.

283. In addition, sales representatives aggressively pushed doctors to prescribe stronger doses of opioids. For example, one Purdue sales representative wrote about how his regional manager would drill the sales team on their upselling tactics:

It went something like this. "Doctor, what is the highest dose of OxyContin you have ever prescribed?" "20mg Q12h." "Doctor, if the patient tells you their pain score is still high you can increase the dose 100% to 40mg Q12h, will you do that?" "Okay." "Doctor, what if that patient then came back and said their pain score was

still high, did you know that you could increase the OxyContin dose to 80mg Q12h, would you do that?" "I don't know, maybe." "Doctor, but you do agree that you would at least Rx the 40mg dose, right?" "Yes."

The next week the representative would see that same doctor and go through the same discussion with the goal of selling higher and higher doses of OxyContin. Stronger doses were more expensive and increased the likelihood of addiction.

284. These misrepresentations were particularly dangerous. Opioid doses at or above 50 MME (morphine milligram equivalents)/day double the risk of overdose compared to 20 MME/day, and 50 MME is equal to just 33 mg of oxycodone. The recommendation of 320 mg every twelve hours is ten times that.

285. In its 2010 Risk Evaluation and Mitigation Strategy ("REMS") for OxyContin, however, Purdue does not address the increased risk of respiratory depression and death from increasing dose, and instead advises prescribers that "dose adjustments may be made every 1-2 days"; "it is most appropriate to increase the q12h dose"; the "total daily dose can usually be increased by 25% to 50%"; and if "significant adverse reactions occur, treat them aggressively until they are under control, then resume upward titration."⁸⁹

286. Purdue, for years, used a marketing theme dubbed "*Individualize the Dose*," which was a euphemism for "*Increase the Dose*," as a means of propounding the false notion that increasing doses of pain killers was in patients' best interests. Staff regularly reported to the Sackler Defendants that sales representatives were continuing the Individualize The Dose campaign.

⁸⁹ Purdue Pharma, L.P., *OxyContin Risk Evaluation and Mitigation Strategy*, Purdue Pharma L.P., <https://web.archive.org/web/20101109172845/http://www.fda.gov/downloads/Drugs/DrugSafetyInformationforPatientsandProviders/UCM220990.pdf>, (last modified Nov. 2010).

287. Endo sponsored a website, www.Painknowledge.com, which claimed that opioids may be increased until “you are on the right dose of medication for your pain,” at which point further dose increases would not be required.

288. Endo also published on its website a patient education pamphlet entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*. In Q&A format, it asked, “If I take the opioid now, will it work later when I really need it?” The response is, “The dose can be increased . . . You won’t ‘run out’ of pain relief.”

289. Marketing Defendants were aware of the greater dangers high dose opioids posed. In 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events” and that studies “appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality.” A study of the Veterans Health Administration from 2004 to 2008 found the rate of overdose deaths is directly related to maximum daily dose.

7. Falsehood #7: Long-term Opioid Use Improves Functioning

290. Despite the lack of evidence of improved function and the existence of evidence to the contrary, the Marketing Defendants consistently promoted opioids for patients’ function and quality of life because they viewed these claims as a critical part of their marketing strategies. In recalibrating the risk-benefit analysis for opioids, increasing the perceived benefits of treatment was necessary to overcome its risks.

291. Janssen, for example, promoted Duragesic as improving patients’ functioning and work productivity through an ad campaign that included the following statements: “[w]ork, uninterrupted,” “[l]ife, uninterrupted,” “[g]ame, uninterrupted,” “[c]hronic pain relief that supports functionality,” and “[i]mprove[s] . . . physical and social functioning.”

292. Purdue noted the need to compete with this messaging, despite the lack of data supporting improvement in quality of life with OxyContin treatment:

Janssen has been stressing decreased side effects, especially constipation, as well as patient quality of life, as supported by patient rating compared to sustained release morphine... We do not have such data to support OxyContin promotion. . . . In addition, Janssen has been using the “life uninterrupted” message in promotion of Duragesic for non-cancer pain, stressing that Duragesic “helps patients think less about their pain.” This is a competitive advantage based on our inability to make any quality of life claims.⁹⁰

293. Despite its acknowledgment that “[w]e do not have such data to support OxyContin promotion,” Purdue ran a full-page ad for OxyContin in the Journal of the American Medical Association, proclaiming, “There Can Be Life With Relief,” and showing a man happily fly-fishing alongside his grandson, implying that OxyContin would help users’ function. This ad earned a warning letter from the FDA, which admonished, “It is particularly disturbing that your November ad would tout ‘Life With Relief’ yet fail to warn that patients can die from taking OxyContin.”⁹¹

294. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “multiple clinical studies” have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients. But the article cited as support for this in fact stated the contrary, noting the absence of long-term studies and concluding, “[f]or functional outcomes, the other analgesics were significantly more effective than were opioids.”

295. A series of medical journal advertisements for OxyContin in 2012 presented “Pain Vignettes”—case studies featuring patients with pain conditions persisting over several months—

⁹⁰ *Pain Killer*, 281.

⁹¹ Chris Adams, *FDA Orders Purdue Pharma To Pull Its OxyContin Ads*, WALL STREET JOURNAL (Jan. 23, 2003), <https://www.wsj.com/articles/SB1043259665976915824>.

that implied functional improvement. For example, one advertisement described a “writer with osteoarthritis of the hands” and implied that OxyContin would help him work more effectively.

296. Similarly, since at least May of 2011, Endo has distributed and made available on its website, www.opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like those of a construction worker or chef, misleadingly implying that the drug would provide long-term pain relief and functional improvement.

297. As noted above, Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which states as “a fact” that “opioids may make it easier for people to live normally.” This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. It assures patients that, “[u]sed properly, opioid medications can make it possible for people with chronic pain to ‘return to normal.’” Similarly, *Responsible Opioid Prescribing* (2007), sponsored and distributed by Teva, Endo, and Purdue, taught that relief of pain by opioids, by itself, improved patients’ function. The book remains for sale online.

298. In addition, Janssen’s *Let’s Talk Pain* website featured a video interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to “continue to function,” falsely implying that her experience would be representative.

299. Endo’s NIPC website, www.Painknowledge.com, claimed that with opioids, “your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse.” In addition to “improved function,” the website touted improved quality of life as a benefit of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC’s

intent to make claims of functional improvement.

300. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been “shown to reduce pain and improve depressive symptoms and cognitive functioning.” The CME was disseminated via webcast.

301. Mallinckrodt’s website, in a section on responsible use of opioids, claims that “[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society.”⁹²

302. The Marketing Defendants’ claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. There are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients’ pain and function long term. The FDA, for years, has made clear through warning letters to manufacturers the lack of evidence for claims that the use of opioids for chronic pain improves patients’ function and quality of life.⁹³ Based upon a review of the existing scientific evidence, the

⁹² Mallinckrodt Pharmaceuticals, Responsible Use, <http://www.mallinckrodt.com/corporate-responsibility/responsible-use>, (last accessed July 16, 2018).

⁹³ The FDA has warned other drug makers that claims of improved function and quality of life were misleading. See Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc’ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis’ opioid, Kadian, had an “overall positive impact on a patient’s work, physical and mental functioning, daily activities, or enjoyment of life.”); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc’ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that “patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience.”). The FDA’s warning letters were available to Defendants on the FDA website.

CDC Guideline concluded that “there is no good evidence that opioids improve pain or function with long-term use.”⁹⁴

303. Consistent with the CDC’s findings, substantial evidence exists demonstrating that opioid drugs are ineffective for the treatment of chronic pain and worsen patients’ health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. The few longer-term studies of opioid use had “consistently poor results,” and “several studies have showed that Opioids for chronic pain may actually worsen pain and functioning . . .”⁹⁵ along with general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.

304. On the contrary, the available evidence indicates opioids may worsen patients’ health and pain. Increased duration of opioid use is strongly associated with increased prevalence of mental health disorders (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization. The CDC Guideline concluded that “[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant.”⁹⁶ According to the CDC, “for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain].”⁹⁷

⁹⁴ CDC Guideline at 20.

⁹⁵ Thomas Frieden and Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, at 1503, 374 New Eng. J. Med., 4/21/16, at 1503. (April 21, 2016).

⁹⁶ CDC Guideline at 2, 18.

⁹⁷ Thomas Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, at 1503, 374 New Eng. J. Med. 1501-1504 (Apr. 21, 2016), doi: 10.1056/NEJMp1515917, <http://www.nejm.org/doi/full/10.1056/NEJMp1515917>.

305. As one pain specialist observed, “opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally.”⁹⁸ In fact, research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.⁹⁹ Another study demonstrated that injured workers who received a prescription opioid for more than seven days during the first six weeks after the injury were 2.2 times more likely to remain on work disability a year later than workers with similar injuries who received no opioids at all.¹⁰⁰ Yet, Marketing Defendants have not acknowledged, retracted, or corrected their false statements.

8. Falsehood #8: Alternative Forms of Pain Relief Pose Greater Risks Than Opioids

306. In materials they produced, sponsored, or controlled, the Marketing Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription non-steroidal anti-inflammatory drugs (“NSAIDs”).

⁹⁸ Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), available at <http://www.nbcms.org/en-us/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747>.

⁹⁹ Jeffrey Dersh, et al., *Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders*, 33(20) Spine 2219-27 (Sept. 15, 2008).

¹⁰⁰ Franklin, GM, et al., *Early opioid prescription and subsequent disability among workers with back injuries: the Disability Risk Identification Study Cohort*, 33 Spine 199, 201-202 (Jan. 15, 2008) doi: 10.1097/BRS.0b013e318160455c, <https://www.ncbi.nlm.nih.gov/pubmed/18197107>.

307. For example, in addition to failing to disclose the risks of addiction, overdose, and death in promotional materials, the Marketing Defendants routinely ignored the risks of hyperalgesia, a “known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time,”¹⁰¹ hormonal dysfunction,¹⁰² decline in immune function; mental clouding, confusion, and dizziness, increased falls and fractures in the elderly,¹⁰³ neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers withdrawal after birth), and potentially fatal interactions with alcohol or with benzodiazepines, which are used to treat anxiety and may be co-prescribed with opioids, particularly to veterans suffering from pain.¹⁰⁴

308. The APF’s *Treatment Options: A Guide for People Living with Pain*, sponsored by Purdue and Cephalon, warned that risks of NSAIDs increase if “taken for more than a period of months,” with no corresponding warning about opioids. The publication falsely attributed 10,000 to 20,000 deaths annually to NSAID overdose, when the figure is actually closer to 3,200.¹⁰⁵

¹⁰¹ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

¹⁰² H.W. Daniell, Hypogonadism in men consuming sustained-action oral opioids, 3(5) J. Pain 377-84 (2001), <https://www.ncbi.nlm.nih.gov/pubmed/14622741>.

¹⁰³ See Bernhard M. Kuschel, et al., *The risk of fall injury in relation to commonly prescribed medications among older people – a Swedish case-control study*, 25 Eur. J. Pub. H. 527-32 (July 31, 2014), doi: 10.1093/eurpub/cku120, <https://www.ncbi.nlm.nih.gov/pubmed/25085470>.

¹⁰⁴ Karen H. Seal, et al., *Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass’n 940-47, (March 7, 2012) doi:10.1001/jama.2012.234, <https://jamanetwork.com/journals/jama/fullarticle/1105046>.

¹⁰⁵ Robert E. Tarone, et al., *Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies*, 11 Am. J. of Therapeutics 17-25 (2004), <https://www.ncbi.nlm.nih.gov/pubmed/14704592>.

309. Janssen sponsored *Finding Relief: Pain Management for Older Adults* (2009) that listed dose limitations as “disadvantages” of other pain medicines but omitted any discussion of risks from increased doses of opioids. *Finding Relief* described the advantages and disadvantages of NSAIDs on one page, and the “myths/facts” of opioids on the facing page. The disadvantages of NSAIDs are described as involving “stomach upset or bleeding,” “kidney or liver damage if taken at high doses or for a long time,” “adverse reactions in people with asthma,” and “can increase the risk of heart attack and stroke.” The only adverse effects of opioids listed are “upset stomach or sleepiness,” which the brochure claims will go away, and constipation.

310. Endo’s NIPC website, www.Painknowledge.org, contained a flyer called “Pain: Opioid Therapy.” This publication listed opioids’ adverse effects but with significant omissions, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

311. In April 2007, Endo sponsored an article aimed at prescribers, published in *Pain Medicine News*, titled “Case Challenges in Pain Management: Opioid Therapy for Chronic Pain.”¹⁰⁶ The article asserted:

Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.¹⁰⁷

312. To help allay these concerns, Endo emphasized the risks of NSAIDs as an alternative to opioids. The article included a case study that focused on the danger of extended use

¹⁰⁶ Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, Pain Med. News, http://www.painmedicinewebs.com/download/BtoB_Opana_WM.pdf, (link no longer available).

¹⁰⁷ *Id.*

of NSAIDs, including that the subject was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids.

313. Additionally, Purdue, acting with Endo, sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

314. As a result of the Marketing Defendants' deceptive promotion of opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.¹⁰⁸

9. Falsehood #9: OxyContin Provides Twelve Hours of Pain Relief

315. Purdue also dangerously misled doctors and patients about OxyContin's duration and onset of action, making the knowingly false claim that OxyContin would provide 12 hours of pain relief for most patients. As laid out below, Purdue made this claim for two reasons. First, it provided the basis for both Purdue's patent and its market niche, allowing it to both protect and differentiate itself from competitors. Second, it allowed Purdue to imply or state outright that

¹⁰⁸ M. Daubresse, et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010*, 51(10) Med. Care, 870-878 (2013). "For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5% of these visits; and referrals to physical therapy remained steady." See also, J. Mafi, et al., *Worsening Trends in the Management and Treatment of Back Pain*, 173(17) J. of the Am Med. Ass'n Internal Med. 1573, 1573 (2013).

OxyContin had a more even, stable release mechanism that avoided peaks and valleys and therefore the rush that fostered addiction and attracted abusers.

316. Purdue promotes OxyContin as an extended-release opioid, but the oxycodone does not enter the body on a linear rate. OxyContin works by releasing a greater proportion of oxycodone into the body upon administration, and the release gradually tapers, as illustrated in the following chart, which was apparently adapted from Purdue's own sales materials.

OxyContin PI Figure, Linear y-axis

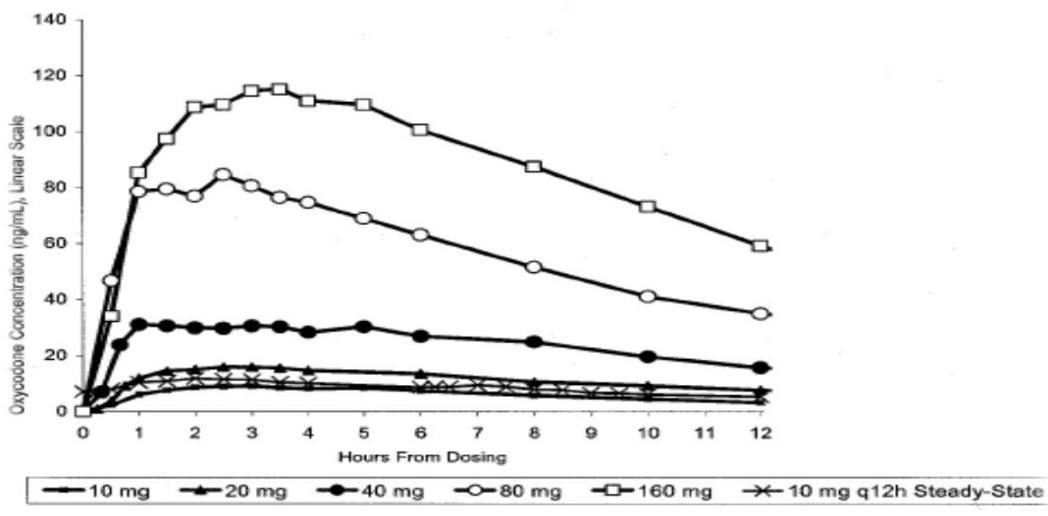


Figure 1

317. The reduced release of the drug over time means that the OxyContin no longer provides the same level of pain relief; as a result, in many patients, OxyContin does not last for the twelve hours for which Purdue promotes it—a fact that Purdue has known at all times relevant to this action.

318. OxyContin tablets provide an initial absorption of approximately 40% of the active medicine. This has a two-fold effect. First, the initial rush of nearly half of the powerful opioid triggers a powerful psychological response. OxyContin thus behaves more like an immediate release opioid, which Purdue itself once claimed was more addicting in its original 1995 FDA-

approved drug label. Second, the initial burst of oxycodone means that there is less of the drug at the end of the dosing period, which results in the drug not lasting for a full twelve hours and precipitates withdrawal symptoms in patients, a phenomenon known as “end of dose” failure. (The FDA found in 2008 that a “substantial number” of chronic pain patients will experience end-of-dose failure with OxyContin.)

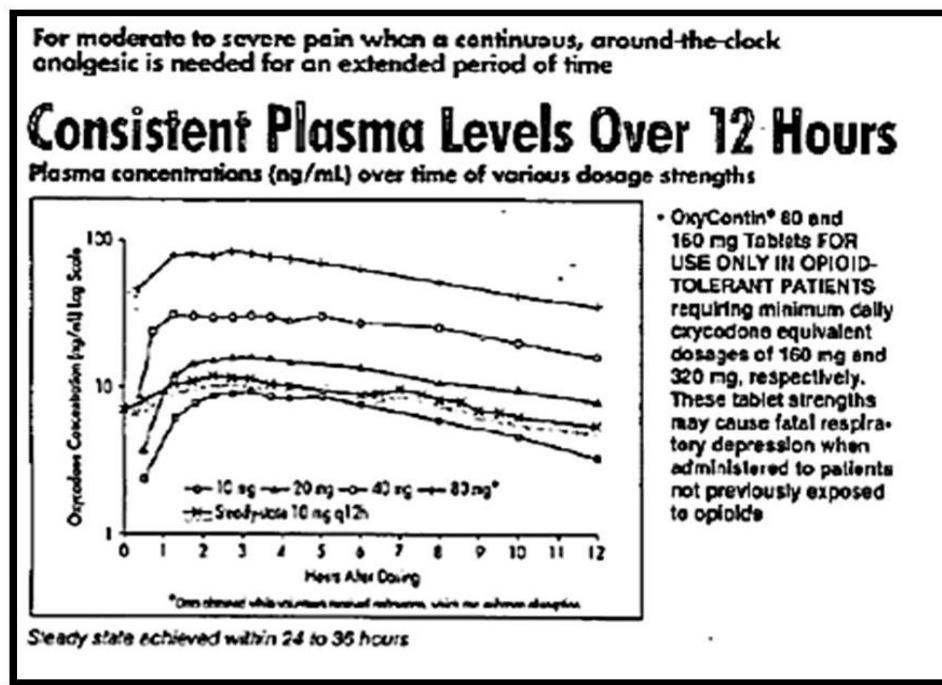
319. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin’s 12-hour dosing “the perfect recipe for addiction.”¹⁰⁹ Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall quantity of opioids they are taking.

320. It was Purdue’s decision to submit OxyContin for approval with 12-hour dosing. While the OxyContin label indicates that “[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours,” that is because Purdue has conducted no such studies.

321. Purdue nevertheless has falsely promoted OxyContin as if it were effective for a full twelve hours. Its advertising in 2000 included claims that OxyContin provides “Consistent Plasma Levels Over 12 Hours.” That claim was accompanied by a chart, mirroring the chart on the previous page. However, this version of the chart deceptively minimized the rate of end-of-dose failure by depicting 10 mg in a way that it appeared to be half of 100 mg in the table’s y-

¹⁰⁹ Harriet Ryan, et al., ‘*You Want a Description of Hell?*’ *OxyContin’s 12-Hour Problem*, LOS ANGELES TIMES (May 5, 2016), <http://www.latimes.com/projects/oxycontin-part1/>.

axis. That chart, shown below, depicts the same information as the chart above, but does so in a way that makes the absorption rate appear more consistent:



322. Purdue's 12-hour messaging was key to its competitive advantage over short-acting opioids that required patients to wake in the middle of the night to take their pills. Purdue advertisements also emphasized "Q12h" dosing. These include an advertisement in the February 2005 *Journal of Pain* and 2006 *Clinical Journal of Pain* featuring an OxyContin logo with two pill cups, reinforcing the twice-a-day message. A Purdue memo to the OxyContin launch team stated that "OxyContin's positioning statement is 'all of the analgesic efficacy of immediate-release oxycodone, with convenient q12h dosing,'" and further that "[t]he convenience of q12h dosing was emphasized as the most important benefit."¹¹⁰

323. Purdue executives therefore maintained the messaging of twelve-hour dosing even when many reports surfaced that OxyContin did not last twelve hours. Instead of acknowledging

¹¹⁰ Purdue Meeting Memo, *OxyContin launch*, LOS ANGELES TIMES (May 5, 2016), <http://documents.latimes.com/oxycontin-launch-1995/>.

a need for more frequent dosing, Purdue instructed its representatives to push higher-strength pills, even though higher dosing carries its own risks, as noted above. Higher dosing also means that patients will experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the LOS ANGELES TIMES, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 MED (morphine equivalent dose) that the CDC Guideline urges prescribers to “avoid” or “carefully justify.”¹¹¹

324. The information that OxyContin did not provide pain relief for a full twelve hours was known to Purdue, and Purdue’s competitors, but was not disclosed to prescribers. Purdue’s knowledge of some pain specialists’ tendency to prescribe OxyContin three times per day instead of two is apparent from MEDWATCH Adverse Event reports for OxyContin.

325. Even Purdue’s competitor, Endo, was aware of the problem; Endo attempted to position its Opana ER drug as offering “durable” pain relief, which Endo understood to suggest a contrast to OxyContin. Opana ER advisory board meetings featured pain specialists citing lack of 12-hour dosing as a disadvantage of OxyContin. Endo even ran advertisements for Opana ER referring to “real” 12-hour dosing.

326. For example, in a 1996 sales strategy memo from a Purdue regional manager, the manager emphasized that representatives should “convinc[e] the physician that there is no need” for prescribing OxyContin in shorter intervals than the recommended 12-hour interval, and instead the solution is prescribing higher doses.”¹¹² One sales manager instructed her team that anything

¹¹¹ CDC Guideline at 16.

¹¹² Southern Region Memo to Mr. B. Gergely, *Sales manager on 12-hour dosing*, LOS ANGELES TIMES (May 5, 2016), <http://documents.latimes.com/sales-manager-on12-hour-dosing-1996/>

shorter than 12-hour dosing “needs to be nipped in the bud. NOW!!”¹¹³

327. Purdue’s failure to disclose the prevalence of end-of-dose failure meant that prescribers were misinformed about the advantages of OxyContin in a manner that preserved Purdue’s competitive advantage and profits, at the expense of patients, who were placed at greater risk of overdose, addiction, and other adverse effects.

10. Falsehood #10: New Formulations of Certain Opioids Successfully Deter Abuse

328. Rather than take the widespread abuse of and addiction to opioids as reason to cease their untruthful marketing efforts, Marketing Defendants Purdue and Endo seized them as an opportunity to compete. These companies developed and oversold “abuse-deterrant formulations” (“ADF”) opioids as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids, as well as an advantage of these expensive branded drugs over other opioids. These Defendants’ false and misleading marketing of the benefits of their ADF opioids preserved and expanded their sales and falsely reassured prescribers thereby prolonging the opioid epidemic. Other Marketing Defendants, including Actavis and Mallinckrodt, also promoted their branded opioids as formulated to be less addictive or less subject to abuse than other opioids.

329. The CDC Guideline confirms that “[n]o studies” support the notion that “abuse-deterrant technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that the technologies “do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes.” Tom Frieden, the former Director of the CDC, reported that his staff could not find “any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death.”

¹¹³ Harriet Ryan, et al., ‘*You Want a Description of Hell?*’ *OxyContin’s 12-Hour Problem*, LOS ANGELES TIMES (May 5, 2016), <http://www.latimes.com/projects/oxycontin-part1/>.

a. Purdue's Deceptive Marketing of Reformulated OxyContin and Hysingla ER

330. Reformulated ADF OxyContin was approved by the FDA in April 2010. It was not until 2013 that the FDA, in response to a citizen petition filed by Purdue, permitted reference to the abuse-deterrent properties in its label. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties and limitations. But in the beginning, the FDA made clear the limited claims that could be made about ADF, noting that no evidence supported claims that ADF prevented tampering, oral abuse, or overall rates of abuse.

331. Purdue introduced reformulated ADF OxyContin shortly before generic versions of OxyContin were to become available. By so doing, Purdue anticipated and countered a threat to its market share and the price it could charge for OxyContin. Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis.

332. Internal documents reveal that the Purdue Defendants knew, and in fact discussed, the fact that the "crush-proof" ADF reformulation would not prevent the vast majority of opioid abuse, which comes from swallowing pills, and that they introduced the product solely for purposes of extending their patent. In 2008, Defendant John Stewart, then CEO, wrote to Defendant Richard Sackler that reformulating OxyContin "will not stop patients from the simple act of taking too many pills."

333. Despite its self-proclaimed good intention, Purdue merely continued its generally deceptive tactics with respect to ADF. Purdue sales representatives regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids. Specifically, Purdue sales representatives:

- a. claimed that Purdue's ADF opioids prevent tampering and that its ADFs could not be crushed or snorted;

- b. claimed that Purdue's ADF opioids reduce opioid abuse and diversion;
- c. asserted or suggested that its ADF opioids are non-addictive or less addictive;
- d. asserted or suggested that Purdue's ADF opioids are safer than other opioids, could not be abused or tampered with, and were not sought out for diversion; and
- e. failed to disclose that Purdue's ADF opioids do not impact oral abuse or misuse.

334. If pressed, Purdue acknowledged that perhaps some “extreme” patients might still abuse the drug but claimed the ADF features protect the majority of patients. These misrepresentations and omissions are misleading and contrary to Purdue's ADF labels, Purdue's own information, and publicly available data.

335. Purdue knew or should have known that reformulated OxyContin is not more tamper-resistant than the original OxyContin and is still regularly tampered with.

336. In 2009, the FDA noted in permitting ADF labeling that “the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse).” In the 2012 medical office review of Purdue's application to include an abuse-deterrence claim in its label for OxyContin, the FDA noted that the overwhelming majority of deaths linked to OxyContin were associated with oral consumption, and that only 2% of deaths were associated with recent injection and only 0.2% with snorting the drug.

337. The FDA's Director of the Division of Epidemiology stated in September 2015 that no data that she had seen suggested the reformulation of OxyContin “actually made a reduction in abuse,” between continued oral abuse, shifts to injection of other drugs (including heroin), and defeat of the ADF mechanism. Even Purdue's own funded research shows that half of OxyContin abusers continued to abuse the drug orally after the reformulation rather than shift to other drugs.

338. A 2013 article presented by Purdue employees, based on review of data from poison control centers, concluded that ADF OxyContin can reduce abuse, but ignored important negative findings. The article revealed that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were more harmful exposures to opioids after the reformulation of OxyContin. In short, the article deceptively emphasized the advantages and ignored the disadvantages of ADF OxyContin.

339. Websites and message boards used by drug abusers, such as www.bluelight.org and www.reddit.com, report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. Purdue has been aware of these methods of abuse for more than a decade.

340. One-third of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, there was no meaningful reduction in opioid abuse overall, as many users simply shifted to other opioids such as heroin.

341. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff was to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated product has a meaningful impact on abuse."¹¹⁴ In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that Purdue never presented the data to the

¹¹⁴ Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting, May 25, 2015, 80 FR 30686.

FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

342. Despite its own evidence of abuse, and the lack of evidence regarding the benefit of Purdue's ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are being abused in large numbers. Purdue's recent advertisements in national newspapers also continues to claim its ADF opioids as evidence of its efforts to reduce opioid abuse, continuing to mislead prescribers, patients, payors, and the public about the efficacy of its actions.

b. Endo's Deceptive Marketing of Reformulated Opana ER

343. Opana ER was particularly likely to be tampered with and abused. That is because Opana ER has lower "bioavailability" than other opioids, meaning that the active pharmaceutical ingredient (the "API" or opioid) does not absorb into the bloodstream as rapidly as other opioids when taken orally. Additionally, when swallowed whole, the extended-release mechanism remains intact, so that only 10% of Opana ER's API is released into the patient's bloodstream relative to injection; when it is taken intranasally, that rate increases to 43%. The larger gap between bioavailability when consumed orally versus snorting or injection, the greater the incentive for users to manipulate the drug's means of administration.

344. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant.

345. Even prior to its approval, the FDA advised Endo that it could not market the new Opana ER as abuse-deterrent.

346. Nonetheless, in August of 2012, Endo submitted a citizen petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted and that it was resistant to injection by syringe. Borrowing a

page from Purdue’s playbook, Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse-deterrence), which would prevent generic copies of original Opana ER.

347. Endo then sued the FDA, seeking to force expedited consideration of its citizen petition. The court filings confirmed Endo’s true motives: in a declaration submitted with its lawsuit, Endo’s chief operating officer indicated that a generic version of Opana ER would decrease the company’s revenue by up to \$135 million per year. Endo also claimed that if the FDA did not block generic competition, \$125 million, the amount Endo spent on developing the reformulated drug to “promote the public welfare”, would be lost.¹¹⁵ The FDA responded that: “Endo’s true interest in expedited FDA consideration stems from business concerns rather than protection of the public health.”¹¹⁶

348. Despite Endo’s purported concern with public safety, not only did Endo continue to distribute original, admittedly unsafe Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers. In fact, Endo claimed in September 2012 to be “proud” that “almost all remaining inventory” of the original Opana ER had “been utilized.”¹¹⁷

349. In its citizen petition, Endo asserted that redesigned Opana ER had “safety advantages.” Endo even relied on its rejected assertion that Opana was less crushable to argue that

¹¹⁵ Plaintiff’s Opposition to Defendants’ and Intervenor’s Motions to Dismiss and Plaintiff’s Reply in Support of Motion for Preliminary Injunction (“Endo Br.”), *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 23 at 20 (D.D.C. Dec.14, 2012).

¹¹⁶ Defendants’ Response to the Court’s November 30, 2012 Order, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 9 at 6 (D.D.C. Dec. 3, 2012).

¹¹⁷ *Id.*; Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl.) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 18-4 (D.D.C. Dec. 9, 2012).

it developed Opana ER for patient safety reasons and that the new formulation would help, for example, “where children unintentionally chew the tablets prior to an accidental ingestion.”¹¹⁸

350. However, in a 2013 decision rejecting the petition, the FDA found that “study data show that the reformulated version’s extended-release features can be compromised when subjected to … cutting, grinding, or chewing.” The FDA also determined that “reformulated Opana ER” could also be “readily prepared for injections and more easily injected[.]” In fact, the FDA warned that preliminary data—including in Endo’s own studies—suggested that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

351. In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER has increased by more than 500%. Endo’s own data, presented in 2014, found that between October 2012 and March 2014, 64% of abusers of Opana ER did so by injection, compared with 36% for the old formulation.¹¹⁹ The transition into injection of Opana ER made the drug even less safe than the original formulation. Injection carries risks of HIV, hepatitis C, and, in reformulated Opana ER’s specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura (TTP), which can cause kidney failure.

352. Publicly, Endo sought to minimize the problem. On a 2013 call with investors, when asked about an outbreak of TTP in Ohio from injecting Opana ER, Endo sought to limit its import by assigning it to “a very, very distinct area of the country.”

353. Despite its knowledge that Opana ER was widely abused and injected, Endo

¹¹⁸ CP, FDA Docket 2012-8-0895, at 2.

¹¹⁹ Theresa Cassidy, et al., *The Changing Abuse Ecology: Implications for Evaluating the Abuse Pattern of Extended-Release Oxymorphone and Abuse-Deterrent Opioid Formulations*, Inflexxion (Sept. 7, 2014), <https://www.inflexxion.com/changing-abuse-ecology-extended-release-oxymorphone/>.

marketed the drug as tamper-resistant and abuse-deterrant. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that based on the company's detailing elsewhere, Endo sales representatives informed doctors that Opana ER was abuse-deterrant, could not be tampered with, and was safe. In addition, sales representatives did not disclose evidence that Opana was easier to abuse intravenously and, if pressed by prescribers, claimed that while outlier patients might find a way to abuse the drug, most would be protected.

354. A review of national surveys of prescribers regarding their "take-aways" from pharmaceutical detailing confirms that prescribers remember being told Opana ER was tamper-resistant. Endo also tracked messages that doctors took from its in-person marketing. Among the advantages of Opana ER, according to participating doctors, was its "low abuse potential." For example, a June 14, 2012 Endo press release announced, "the completion of the company's transition of its Opana ER franchise to the new formulation designed to be crush resistant."

355. The press release further stated that: "We firmly believe that the new formulation of Opana ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers." The press release described the old formulation of Opana as subject to abuse and misuse, but failed to disclose the absence of evidence that reformulated Opana was any better. In September 2012, another Endo press release stressed that reformulated Opana ER employed "INTAC Technology" and continued to describe the drug as "designed to be crush-resistant."

356. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant." A January 2013 article in Pain Medicine News, based in part on an Endo press release, described Opana ER as "crush-resistant." This article was posted on the *Pain Medicine News* website, which was accessible to patients and prescribers.

357. In 2015, the Indiana Department of Public Health determined that an HIV outbreak in Southeastern Indiana was linked to injection of Opana,¹²⁰ the first documented HIV outbreak in the United States associated with injection of a prescription painkiller. After the outbreak, the FDA required “that Endo Pharmaceuticals remove [Opana ER] from the market.” The agency sought removal “based on its concern that the benefits of the drug may no longer outweigh its risks.”¹²¹

358. In March 2017, because Opana ER could be “readily prepared for injection” and was linked to outbreaks of HIV and TTP, an FDA advisory committee recommended that Opana be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017.¹²² Endo announced on July 6, 2017 that it would agree to stop marketing and selling Opana ER.¹²³ However, by this point, the damage had been done. Even then, Endo continued to insist, falsely, that it “has taken significant steps over the years to combat misuse and abuse.”

c. Other Marketing Defendants’ Misrepresentations Regarding Abuse Deterrence

359. Mallinckrodt promoted both Exalgo (extended-release hydromorphone) and Xartemis XR (oxycodone and acetaminophen) as specifically formulated to reduce abuse. For example, Mallinckrodt’s promotional materials stated that “the physical properties of EXALGO

¹²⁰ Press Release, State of Ind. Health Dep’t, HIV Outbreak in Southeastern Indiana, (Feb. 25, 2015), http://www.in.gov/activecalendar/EventList.aspx?fromdate=1/1/2015&todate=12/31/2015&display=Month&type=public&eventidn=210259&view=EventDetails&information_id=211489.

¹²¹ Jen Christensen, *FDA wants Opioid Painkiller Pulled off Market*, CNN (June 8, 2017), <https://www.cnn.com/2017/06/08/health/fda-opioid-opana-er-bn/index.html>; Press Release, U.S. Food & Drug Admin., FDA Requests Removal of Opana ER for Risks Related to Abuse (June 8, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>.

¹²² Press Release, FDA, FDA requests removal of Opana ER for risks related to abuse, (June 8, 2017), available at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>

¹²³ Press Release, Endo International plc, Endo Provides Update on Opana ER, (July 6, 2017), available at <https://www.prnewswire.com/news-releases/endo-provides-update-on-opana-er-300484191.html>.

may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving.”¹²⁴ One member of the FDA’s Controlled Substance Staff, however, noted in 2010 that hydromorphone has “a high abuse potential comparable to oxycodone” and further stated that “we predict that Exalgo will have high levels of abuse and diversion.”

360. With respect to Xartemis XR, Mallinckrodt’s promotional materials stated that “XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients.”¹²⁵ In anticipation of Xartemis XR’s approval, Mallinckrodt added 150-200 sales representatives to promote it, and CEO Mark Trudeau said the drug could generate “hundreds of millions in revenue.”¹²⁶

361. While Marketing Defendants promote patented technology as the solution to opioid abuse and addiction, none of their “technology” addresses the most common form of abuse—oral ingestion—and their statements regarding abuse-deterring formulations give the misleading impression that these reformulated opioids can be prescribed safely.

362. In sum, each of the nine categories of misrepresentations discussed above regarding the use of opioids to treat chronic pain was either not supported by or was contrary to the scientific evidence. In addition, the Defendants’ misrepresentations and omissions as set in this Complaint are misleading and contrary to the Marketing Defendants’ products’ labels.

¹²⁴ Mallinckrodt Press Release, Medtronic, *FDA Approves Mallinckrodt’s EXALGO® (hydromorphone HCl) Extended-Release Tablets 32 mg (CII) for Opioid-Tolerant Patients with Moderate-to-Severe Chronic Pain* (Aug. 27, 2012), available at <http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2004159>.

¹²⁵ Mallinckrodt, *Responsible Use of Opioid Pain Medications* (Mar. 7, 2014).

¹²⁶ Samantha Liss, *Mallinckrodt banks on new painkillers for sales*, ST. LOUIS BUSINESS JOURNAL (Dec. 30, 2013), <http://argentcapital.com/mallinckrodt-banks-on-new-painkillers-for-sales/>

B. The Marketing Defendants Disseminated Their Misleading Messages About Opioids Through Multiple Direct and Indirect Channels

363. The Marketing Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients throughout the United States. The Marketing Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the country, including those communities served by Plaintiffs.

364. Across the pharmaceutical industry, “core message” development is funded and overseen on a national basis by the drug manufacturers’ corporate headquarters. This comprehensive approach ensures that the Marketing Defendants’ messages are accurately and consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. The Marketing Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

365. The Marketing Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons (the company employees who respond to physician inquiries); centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. The Marketing Defendants’ sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

366. The Marketing Defendants utilized various channels to carry out their marketing scheme of targeting the medical community and patients with deceptive information about opioids: (1) direct, targeted communications with prescribers by sales representatives or “detailers;” (2)

“Front Groups” with the appearance of independence from the Marketing Defendants; (3) so-called “key opinion leaders” (“KOLs”), that is, doctors who were paid by the Marketing Defendants to promote their pro-opioid message; (4) CME programs controlled and/or funded by the Marketing Defendants; (5) branded advertising; (6) unbranded advertising; (7) publications; and (8) speakers bureaus and programs.

1. The Marketing Defendants Used “Detailers” To Directly Disseminate Their Misrepresentations to Prescribers

367. The Marketing Defendants’ sales representatives executed carefully crafted marketing tactics, developed at the highest rungs of their corporate ladders, to reach targeted doctors and hospitals with centrally orchestrated messages. The Marketing Defendants’ sales representatives also distributed third-party marketing material to their target audience that was deceptive. The Marketing Defendants’ direct contact with prescribers was, by far, their most important means of disseminating the false narrative and increasing opioid prescriptions, and, accordingly, their sales.

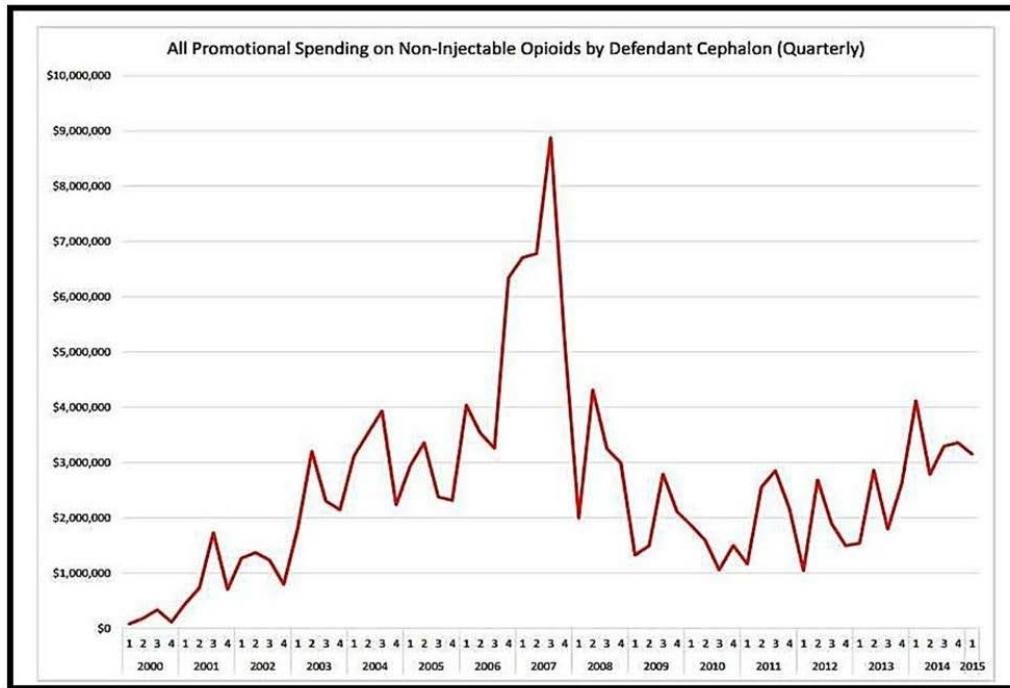
368. Each Marketing Defendant promoted opioids through sales representatives (also called “detailers”) and, in consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that small group speaker programs were designed to reach out to individual prescribers. By establishing close relationships with doctors, the Marketing Defendants were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to promote their opioids and to allay individual prescribers’ concerns about prescribing opioids for chronic pain.

369. In accordance with common industry practice, the Marketing Defendants purchased and closely analyzed prescription sales data from IMS Health (now IQVIA), a healthcare data collection, management, and analytics corporation. This data allowed them to precisely track the

rates of initial and renewal prescribing by individual doctors, which allowed them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above.

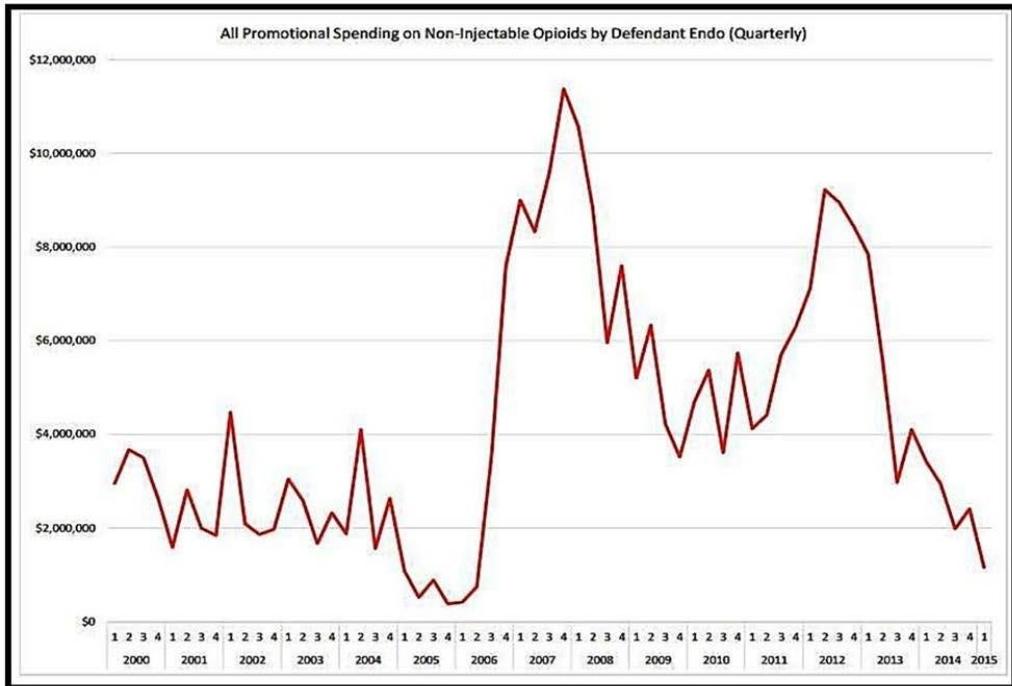
370. Marketing Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Marketing Defendants spent \$166 million on detailing branded opioids to doctors. This amount is twice as much as Marketing Defendants spent on detailing in 2000. The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$13 million by Teva, and \$10 million by Endo.

371. Cephalon's quarterly spending steadily climbed from below \$1 million in 2000 to more than \$3 million in 2014 (and more than \$13 million for the year), with a peak, coinciding with the launch of Fentora, of more than \$27 million in 2007, as shown below:

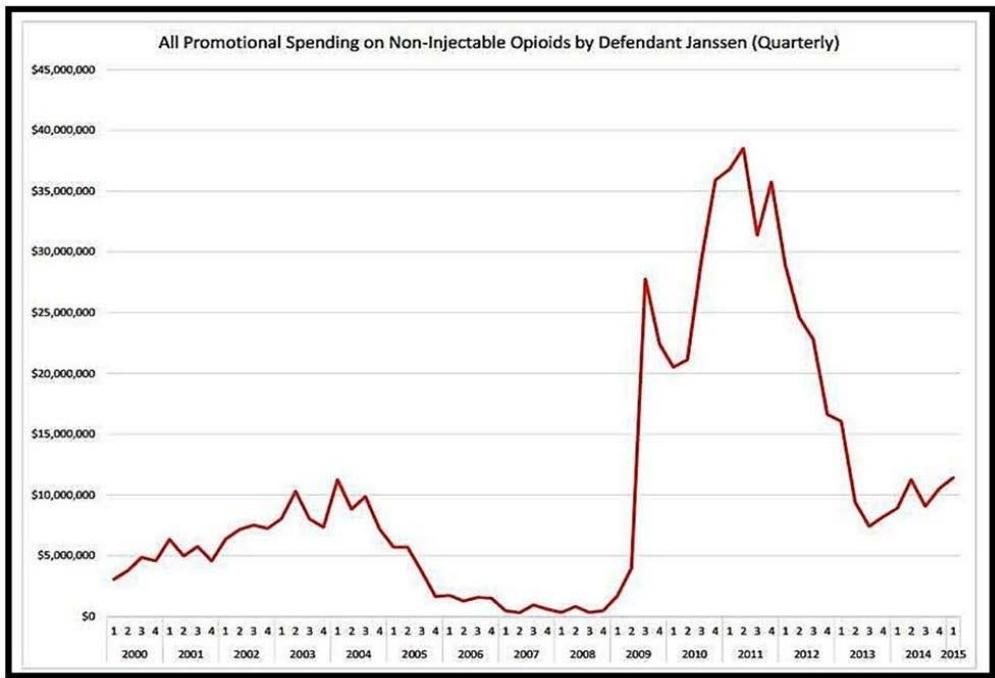


372. Endo's quarterly spending went from the \$2 million to \$4 million range in 2000-2004 to more than \$10 million following the launch of Opana ER in mid-2006 (and more than \$38

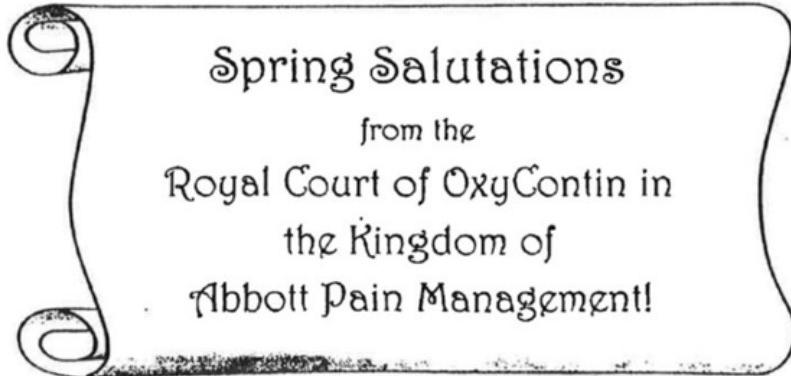
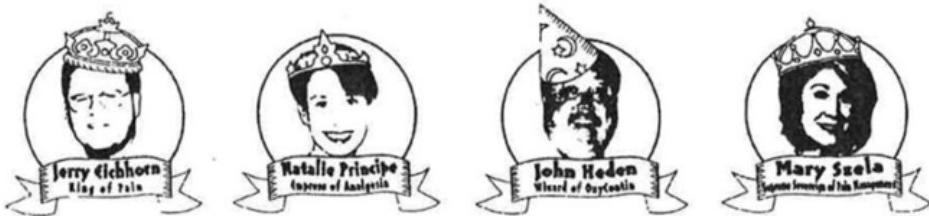
million for the year in 2007) and more than \$8 million coinciding with the launch of a reformulated version in 2012 (and nearly \$34 million for the year), as shown below:



373. Janssen's quarterly spending dramatically rose from less than \$5 million in 2000 to more than \$30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at \$142 million for 2011), as shown below:



374. Abbott, which was tasked with marketing Purdue's products to hospitals, heavily incentivized its staff to push OxyContin, offering \$20,000 cash prizes and luxury vacations to top performers. Abbott's almost religious zeal to sell the drug is evident in the wide use of terminology from the Middle Ages Crusades: Sales reps were called "royal crusaders" and "knights" in internal documents, and they were supervised by the "Royal Court of OxyContin" – executives referred to in memos as the "Wizard of OxyContin," "Supreme Sovereign of Pain Management," and the "Empress of Analgesia." The head of pain care sales, Jerry Eichorn, was the "King of Pain," and Signed memos simply as "King."



375. At Purdue, aggressive and frequent visits to prescribers was always its most important marketing technique. The Sackler Defendants set targets for each representative to visit over 7 prescribers per day, and closely monitored actual data. Some doctors were visited multiple times per week. The pressure on sales representatives, and on prescribers, was relentless, and was dictated by the Sackler Defendants.

376. Each of these in-person sales visits cost Purdue money — on average more than \$200 per visit. But Purdue made that money back many times over, because it convinced doctors to prescribe its addictive drugs. When Purdue identified a doctor as a profitable target, Purdue visited the doctor frequently: often weekly, sometimes almost every day. Purdue salespeople asked doctors to list specific patients they were scheduled to see and pressed the doctors to commit to put the patients on Purdue opioids. By the time a patient walked into a clinic, the doctor, in Purdue's words, had already "guaranteed" that he would prescribe Purdue's drugs.

377. Purdue judged its sales representatives by how many opioids they got doctors to prescribe. Sales representatives who generated the most prescriptions won bonuses and prizes.

These incentives included a “Toppers Club sales contest” for sales representatives to win bonuses, based on how much a representative increased OxyContin use in her territory and how much the representative increased the broader prescribing of opioids — the same “availability of product” and “prescribing practices” factors that worsen the risk of diversion and abuse.

378. Purdue continued to incentivize its representatives to sell opioids even after some competitors had ended that practice. Representatives who failed to get enough patients on opioids were placed on probation, put on performance improvement plans, and they would be threatened with loss of their jobs if they did not generate more opioid sales. Those unable to generate more sales were fired. In 2015 alone, Purdue replaced 14% of its sales representatives and 20% of its District Managers for failing to create enough opioid sales.

379. Sales representatives focused on prolific (and potentially prolific) prescribers, described internally at Purdue as “core,” “super core,” and “high potential” prescribers at times, even though the Marketing Defendants were all well aware of the heightened risk of improper prescriptions and diversion through these prescribers. Defendant Richard Sackler once chastised Defendant Gasdia for Purdue’s managers permitting sales representatives to target “non-high potential prescribers,” asking “[h]ow can our managers have allowed this to happen?” Richard Sackler personally insisted that sales representatives push the doctors who prescribed the most drugs.

380. To make sure doctors prescribed more opioids, Purdue tracked doctors’ prescriptions, visited their offices, bought them meals, and asked them to put specific patients on Purdue drugs. Purdue selected doctors for target lists based on its estimates of which doctors could be influenced to increase opioid prescriptions the most. Purdue managers told representatives to visit most often the doctors who were most likely to change their prescribing to benefit Purdue.

Purdue Sales representatives visited Purdue's targets an average of more than 200 times per year **each**. Those visits cost Purdue more than \$40,000 for each doctor. Purdue did not spend \$40,000 per doctor so sales representatives could watch doctors write prescriptions that they were already going to write anyway. Instead, Purdue paid to lobby these doctors because Purdue knew its representatives would convince them to put more patients on opioids, at higher doses, for longer periods. Those extra prescriptions paid back Purdue's investment many times over.

381. As of the fourth quarter of 2013, Purdue employed 632 sales representatives and, during that quarter they visited prescribers 176,227 times – an annualized rate of over 700,000 visits. Purdue's budget for Sales and Promotion for 2013 was \$312,563,000. In 2013, Purdue spent over \$9 million on meals alone for its prescribers.

382. The sales visits of its staff were so important to the Sackler Defendants, Defendant Richard Sackler himself went into the field in 2013 to promote opioids to doctors alongside a sales representative. Defendant Gasdia and Purdue's Chief Compliance Officer were well aware that this was "a potential compliance risk." To make sure the Sacklers' involvement in marketing stayed secret, staff instructed: "Richard needs to be mum and be anonymous." When he returned, Richard Sackler argued to the Vice President of Sales that a legally required warning about Purdue's opioids wasn't needed. He asserted that the warning "implies a danger of untoward reactions and hazards that simply aren't there." Richard insisted there should be "less threatening" ways to describe Purdue opioids.

383. Purdue intensified its marketing efforts in subsequent years, in an effort to counteract decreasing sales (sales of OxyContin peaked in 2010, and decreased somewhat in subsequent years). For 2018, the Sacklers approved a target for sales representatives to visit

prescribers 1,050,000 times — almost double the number of sales visits they had ordered during the peak of OxyContin sales in 2010.

384. For its opioid Actiq, Cephalon also engaged in direct marketing in direct contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

2. Hospitals Were Directly Targeted by the Marketing Defendants

385. From the beginning, hospitals were directly targeted by the Marketing Defendants. Internal documents from the 1995 "OxyContin Launch" orchestrated by Purdue and Abbott (1) identified "hospital pharmacists" as among their "audience," (2) identified "hospitals" among their "institutional targets," (3) identified an objective of "[f]ormulary acceptance in 75% of hospitals for first twelve months," and (4) identified an objective of developing a "successful distribution program" to "hospitals."

386. In 1996, Defendant Purdue made a deal with pharmaceutical giant Abbott Laboratories, under which Abbott's sales force would promote Purdue's lead opioid, OxyContin, in hospitals.¹²⁷ Abbott's co-promotion of OxyContin was, in the words of Abbott's counsel, by terms of its contract, dedicated to "hospitals, surgical centers and hospital-based surgeons." Promoting the use of OxyContin for "postoperative pain" and "support[ing] the Abbott agreement" were paramount objectives identified in Purdue internal documents. In a July 1997 internal memo, Purdue's then vice-president told seven members of the Sackler family that Purdue had "been pressuring Abbott to increase their activity toward surgeons," and that Abbott had responded with

¹²⁷ "Abbott and Purdue consciously targeted hospitals. [Purdue] representatives will work with their Abbott counterparts to make calls on all Pharmacy and Therapeutic (P&T) communities." "[S]ales force will provide the *appropriate* clinical data necessary to continue to add OxyContin Tablets to hospital formularies." 2002 Purdue Budget Plan, <https://khn.org/news/purdue-and-the-oxycontin-files/> (last visited Aug. 20, 2018) (emphasis added).

a “new emphasis on OxyContin and their dedication of significant resources to this task.”

387. “Abbott and Purdue consciously targeted hospitals. [Purdue] representatives will work with their Abbott counterparts to make calls on all Pharmacy and Therapeutic (P&T) communities.” “[S]ales force will provide the *appropriate* clinical data necessary to continue to add OxyContin Tablets to hospital formularies.”¹²⁸

388. Initial plans called for marketing to “[a]ll 1,200 cancer centers,” “[a]ll 1,200 major teaching institutions,” and “[a]ll 2,500 community hospitals with >= 100 beds.” The hospital marketing plan further entailed the following actions:

- The Purdue Frederick sales force should call on all hospital P&T committees to gain hospital formulary acceptance during the first three months of launch. This effort would entail contacting directors of pharmacies in an effort to gain formulary acceptance of OxyContin.
- Educate MD’s/RN’s/RPH’s regarding the advantages of OxyContin over other Step 2 opioids for cancer patients. The promotional effort should focus on the ease of use and the reduced administration time. If available, clinical outcomes studies, showing improved quality of life and cost effectiveness, should be used to convince the house staff to use OxyContin as their opioid of choice.
- Educational lectures should be held through the Speakers’ Bureau program during grand rounds, tumor boards, etc. The Purdue Frederick Speakers’ Bureau should educate the house staff about the benefits of OxyContin, while presenting clinical study data.
- Educational symposia should be conducted through the use of satellite teleconferencing to various cancer centers and major teaching institutions across the country, offering CME credits to MD’s/RN’s/RPH’s and focus on the implementation of the AHCPR Clinical Practice Guideline for the Management of Cancer Pain and the results of clinical trials with OxyContin.
- Target the top 100 MS CONTIN/Duragesic hospitals and offer them a special pain management day where our OxyContin clinical investigators will train the staff on the use of OxyContin.

¹²⁸ 2002 Purdue Budget Plan, <https://khn.org/news/purdue-and-the-oxycontin-files/> (last visited Aug. 20, 2018) (emphasis added).

389. A 1997 Abbott document indicated that prescriptions written by “Abbott MD’s” comprised 25% of all OxyContin prescriptions. In addition, Purdue budget records reveal details of the payments to Abbott for its OxyContin work, which were termed “commissions.” From 1996 through 2002, Abbott was paid \$374 million in commissions, according to those documents. Total sales of the drug during that time were nearly \$5 billion. From 2003-06, OxyContin sales were nearly \$6 billion. From 1996-2005, inclusive, Abbott’s “commissions” exceeded \$500 million.

3. The Marketing Defendants Deceptively Directed Front Groups to Promote Opioid Use

390. Patient advocacy groups and professional associations also became vehicles to reach prescribers, patients, and policymakers. Marketing Defendants exerted influence and effective control over the messaging by these groups by providing major funding directly to them, as well as through KOLs who served on their boards. These “Front Groups” put out patient education materials, treatment guidelines and CMEs that supported the use of opioids for chronic pain, overstated the benefits of opioids, and understated their risks.¹²⁹ Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages—often at the expense of the Front Groups own constituencies.

391. “Patient advocacy organizations and professional societies like the Front Groups ‘play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public.’”¹³⁰ “Even small organizations—

¹²⁹ U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members’ Office, *Fueling an Epidemic, Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups* (Feb. 12, 2018),

<https://www.hslc.org/?abstract&did=808171> (“Fueling an Epidemic”), at p. 3.

¹³⁰ *Id.* at p. 2.

with ‘their large numbers and credibility with policymakers and the public’—have ‘extensive influence in specific disease areas.’ Larger organizations with extensive funding and outreach capabilities ‘likely have a substantial effect on policies relevant to their industry sponsors.’”¹³¹ Indeed, the U.S. Senate’s report, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*,¹³² which arose out of a 2017 Senate investigation and, drawing on disclosures from Purdue, Janssen, Insys, and other opioid manufacturers, “provides the first comprehensive snapshot of the financial connections between opioid manufacturers and advocacy groups and professional societies operating in the area of Office opioids policy,”¹³³ found that the Marketing Defendants made millions of dollars’ worth of contributions to various Front Groups.¹³⁴

392. The Marketing Defendants also “made substantial payments to individual group executives, staff members, board members, and advisory board members” affiliated with the Front Groups subject to the Senate Committee’s study.¹³⁵

393. As the Senate’s *Fueling an Epidemic* Report found, the Front Groups “amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain.”¹³⁶ They also “lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for over prescription and misbranding.”¹³⁷

¹³¹ *Id.*

¹³² *Id.* at p. 1.

¹³³ *Id.*

¹³⁴ *Id.* at p. 3.

¹³⁵ *Id.* at p. 10.

¹³⁶ *Id.* at 12-15.

¹³⁷ *Id.* at 12.

394. The Marketing Defendants took an active role in guiding, reviewing, and approving many of the false and misleading statements issued by the Front Groups, ensuring that Defendants were consistently in control of their content. By funding, directing, editing, approving, and distributing these materials, Defendants exercised control over and adopted their false and deceptive messages and acted in concert with the Front Groups and through the Front groups, with each working with the other to deceptively promote the use of opioids for the treatment of chronic pain.

a. American Pain Foundation

395. The most prominent of the Front Groups was the American Pain Foundation (“APF”). While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from Defendants Purdue, Endo, Janssen and Cephalon. APF received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. Endo was APF’s largest donor and provided more than half of its \$10 million in funding from 2007 to 2012.

396. For example, APF published a guide sponsored by Cephalon and Purdue titled *Treatment Options: A Guide for People Living with Pain* and distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report. This guide contains multiple misrepresentations regarding opioid use which are discussed *supra*.

397. APF also developed the National Initiative on Pain Control (“NIPC”), which ran a facially unaffiliated website, www.painknowledge.org. NIPC promoted itself as an education initiative led by its expert leadership team, including purported experts in the pain management field. NIPC published unaccredited prescriber education programs (accredited programs are

reviewed by a third party and must meet certain requirements of independence from pharmaceutical companies), including a series of “dinner dialogues.” But it was Endo that substantially controlled NIPC, by funding NIPC projects, developing, specifying, and reviewing its content, and distributing NIPC materials. Endo’s control of NIPC was such that Endo listed it as one of its “professional education initiative[s]” in a plan Endo submitted to the FDA. Yet, Endo’s involvement in NIPC was nowhere disclosed on the website pages describing NIPC or on www.painknowledge.org. Endo estimated it would reach 60,000 prescribers through NIPC.

398. APF was often called upon to provide “patient representatives” for the Marketing Defendants’ promotional activities, including for Purdue’s “*Partners Against Pain*” and Janssen’s “*Let’s Talk Pain*. ” Although APF presented itself as a patient advocacy organization, it functioned largely as an advocate for the interests of the Marketing Defendants, not patients. As Purdue told APF in 2001, the basis of a grant to the organization was Purdue’s desire to strategically align its investments in nonprofit organizations that shared its business interests.

399. In practice, APF operated in close collaboration with Defendants, submitting grant proposals seeking to fund activities and publications suggested by Defendants and assisting in marketing projects for Defendants.

400. This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a “Master Consulting Services” Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF’s work related to a specific promotional project. Moreover, based on the assignment of particular Purdue “contacts” for each project and APF’s periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that

project. The agreement gave Purdue—but not APF—the right to end the project (and, thus, APF’s funding) for any reason.

401. APF’s Board of Directors was largely comprised of doctors who were on the Marketing Defendants’ payrolls, either as consultants or as speakers for medical events. The close relationship between APF and the Marketing Defendants demonstrates APF’s lack of independence in its finances, management, and mission, and APF’s willingness to allow Marketing Defendants to control its activities and messages supports an inference that each Defendant that worked with it was able to exercise editorial control over its publications—even when Defendants’ messages contradicted APF’s internal conclusions.

402. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF’s board voted to dissolve the organization “due to irreparable economic circumstances.” APF then “cease[d] to exist, effective immediately.” Without support from Marketing Defendants, to whom APF could no longer be helpful, APF was no longer financially viable.

b. American Academy of Pain Medicine and the American Pain Society

403. The American Academy of Pain Medicine (“AAPM”) and the American Pain Society (“APS”) are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a “consensus” statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.¹³⁸ The Chair of the committee that issued the statement, Dr. J. David Haddox,

¹³⁸ *The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997), available at <http://www.stgeorgeutah.com/wp-content/uploads/2016/05/OPIOIDES.DOLORCRONICO.pdf> (last accessed Aug. 1, 2018).

was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Russell Portenoy, who was also a spokesperson for Purdue. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website.

404. AAPM's corporate council includes Purdue, Depomed, Teva and other pharmaceutical companies. AAPM's past presidents include Haddox (1998), Dr. Scott Fishman ("Fishman") (2005), Dr. Perry G. Fine ("Fine") (2011) and Dr. Lynn R. Webster ("Webster") (2013), all of whose connections to the opioid manufacturers are well-documented as set forth below.

405. Fishman, who also served as a KOL for Marketing Defendants, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."¹³⁹

406. AAPM has received over \$2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations.

407. More specifically, Purdue paid \$725,584.95 from 2012-2017 to AAPM.¹⁴⁰ Janssen paid \$83,975 from 2012-2017 to AAPM.¹⁴¹ Insys paid \$57,750 from 2012-2017 to AAPM.¹⁴² Endo funded AAPM CMEs. Teva is on AAPM's corporate relations council.

¹³⁹ Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), available at <http://www.medscape.org/viewarticle/500829>.

¹⁴⁰ *Id.*

¹⁴¹ *Fueling an Epidemic Part Two.*

¹⁴² *Id.*

408. As to APS, Purdue paid \$542,259.52 from 2012-2017.¹⁴³ Janssen paid \$88,500 from 2012-2017.¹⁴⁴ Insys paid \$22,965 from 2012-2017.¹⁴⁵

409. AAPM describes its annual meeting as an “exclusive venue” for offering Continuing Medical Education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids – 37 out of roughly 40 at one conference alone.

410. AAPM’s staff understood that they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

411. In 1996, AAPM and APS jointly issued a consensus statement, “The Use of Opioids for the Treatment of Chronic Pain,” which endorsed opioids to treat chronic pain and claimed that the risk of a patients’ addiction to opioids was low. Dr. David Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM’s website until 2011.

412. AAPM and APS issued their own guidelines in 2009 (“2009 Guidelines”). AAPM, with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and continued to recommend the use of opioids to treat chronic pain.

¹⁴³ *Fueling an Epidemic Report Part Two, Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, U.S. Senate Homeland Security & Governmental Affairs Committee, <https://www.hsdl.org/?abstract&did=808171> (last accessed August 1, 2018) (hereinafter referred to as “*Fueling an Epidemic Part Two*”)

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOL Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue. Of these individuals, six received support from Purdue, eight from Teva, nine from Janssen, and nine from Endo.

413. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel School of Medicine, who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

414. The 2009 Guidelines have been a particularly effective channel of deception. They have influenced not only treating physicians, but also the scientific literature on opioids; they were reprinted in the Journal of Pain, have been cited hundreds of times in academic literature, were disseminated during the relevant time period, and were and are available online. Treatment guidelines are especially influential with primary care physicians and family doctors to whom Marketing Defendants promoted opioids and whose lack of specialized training in pain management and opioids makes them more reliant on, and less able to evaluate, these guidelines.

415. For that reason, the CDC has recognized that treatment guidelines can "change prescribing practices."¹⁴⁶

416. The 2009 Guidelines are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain.

417. The Marketing Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions, their involvement in the development

¹⁴⁶ Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain*, (March 15, 2016), <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>, (hereinafter "2016 CDC Guideline").

of the Guidelines, or their financial backing of the authors of these Guidelines. For example, a speaker presentation prepared by Endo in 2009 titled *The Role of Opana ER in the Management of Moderate to Severe Chronic Pain* relies on the AAPM/APS 2009 Guidelines while omitting their disclaimer regarding the lack of evidence for recommending the use of opioids for chronic pain.

c. FSMB

418. The Federation of State Medical Boards (“FSMB”) is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians.

419. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

420. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (“1998 Guidelines”) was produced “in collaboration with pharmaceutical companies.” The 1998 Guidelines—that the pharmaceutical companies helped author—taught not that opioids could be appropriate in only limited cases after other treatments had failed, but that opioids were “essential” for treatment of chronic pain, including as a first prescription option.

421. A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing*, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in Perry County.

422. FSMB's 2007 publication *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Purdue, Endo and Cephalon. Purdue paid \$100,000 for the printing and distribution of FSMB's Guidelines.¹⁴⁷

423. The publication also received support from the American Pain Foundation (APF) and the American Academy of Pain Medicine (AAPM). The publication was written by Dr. Fishman, and Dr. Fine served on the Board of Advisors. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed by state medical boards.¹⁴⁸ The FSMB website describes the book as "the leading continuing medical education (CME) activity for prescribers of opioid medications." This publication asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins; that pain is under-treated, and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient.¹⁴⁹

424. The Marketing Defendants relied on the 1998 Guidelines to convey the alarming message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

¹⁴⁷ John Fauber, *Follow the Money: Pain, Policy, and Profit*, MILWAUKEE JOURNAL SENTINEL/MEDPAGE TODAY (Feb. 19, 2012), <https://www.medpagetoday.com/neurology/painmanagement/31256>.

¹⁴⁸ Email from Dr. Scott Fishman to Charles Ornstein, ProPublica (Dec. 15, 2011), <https://assets.documentcloud.org/documents/279033/fishman-responses-to-propublica.pdf>.

¹⁴⁹ Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide* 8-9 (Waterford Life Sciences 2007).

425. Dr. Fishman said that he did not receive any payments from FSMB or any royalties from the publisher because he wanted to avoid the perception of a potential conflict of interest in his authorship of the book or for the ongoing efforts of FSMB. This is because prior to 2011, he had been scrutinized for his involvement with the front groups/manufacturers and accepting payments.¹⁵⁰

426. The Manufacturing Defendants made additional contributions to the FSMB to further their misleading advertising. For example, Purdue paid FSMB \$822,400.06 over 8 years.¹⁵¹ Cephalon paid FSMB \$180,000 over a 3-year period, 2007-2008 and 2011.¹⁵² Endo paid FSMB \$371,620 over a 5-year period.¹⁵³ Mallinckrodt paid FSMB \$100,000 in 2011.¹⁵⁴

d. The Alliance for Patient Access

427. Founded in 2006, the Alliance for Patient Access (“APA”) is a self-described patient advocacy and health professional organization that styles itself as “a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care.”¹⁵⁵ It is run by Woodberry Associates LLC, a lobbying firm that was also established in

¹⁵⁰ Email from Dr. Scott Fishman to Charles Ornstein, ProPublica (Dec. 15, 2011), <https://assets.documentcloud.org/documents/279033/fishman-responses-to-propublica.pdf>.

¹⁵¹ Letter from Humayun J. Chaudhry, President and CEO, FSMB, to the Hon. Max Baucus and Hon. Charles Grassley, U.S. Senate (June 8, 2012), <https://www.documentcloud.org/documents/3109089-FSMB-Response-Letter-to-US-Senate.html>.

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ The Alliance for Patient Access, *About AfPA*, <http://allianceforpatientaccess.org/about-afpa/#membership> (last accessed August 1, 2018). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.

2006.¹⁵⁶ As of June 2017, the APA listed 30 “Associate Members and Financial Supporters.” The list includes J&J, Endo, Mallinckrodt, Purdue, and Cephalon.

428. APA’s board members have also directly received substantial funding from pharmaceutical companies.¹⁵⁷ For instance, board vice president Dr. Srinivas Nalamachu (“Nalamachu”), who practices in Kansas, received more than \$800,000 from 2013 through 2015 from pharmaceutical companies—nearly all of it from manufacturers of opioids or drugs that treat opioids’ side effects, including from defendants Endo, Insys, Purdue and Cephalon. Nalamachu’s clinic was raided by FBI agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys.¹⁵⁸ Other board members include Dr. Robert A. Yapundich from North Carolina, who received \$215,000 from 2013 through 2015 from pharmaceutical companies, including payments by defendants Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than \$240,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Mallinckrodt and Cephalon; Dr. Howard Hoffberg from Maryland, who received \$153,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Purdue, Insys, Mallinckrodt and Cephalon; and Dr. Robin K. Dore from California, who received \$700,000 between 2013 and 2015 from pharmaceutical companies.

¹⁵⁶ Mary Chris Jaklevic, *Non-profit Alliance for Patient Access uses journalists and politicians to push Big Pharma’s agenda*, HEALTH NEWS REVIEW (Oct. 2, 2017), <https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/> (“Jaklevic, *Non-profit Alliance for Patient Access*”).

¹⁵⁷ All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica’s Dollars for Docs database, available at <https://projects.propublica.org/docdollars/>.

¹⁵⁸ Andy Marso, *FBI seizes records of Overland Park pain doctor tied to Insys*, KANSAS CITY STAR (July 19, 2017), <http://www.kansascity.com/news/business/health-care/article162569383.html>.

429. Among its activities, APA issued a “white paper” titled “*Prescription Pain Medication: Preserving Patient Access While Curbing Abuse.*”¹⁵⁹ Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.

In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives. . .

We cannot merely assume that these programs will reduce prescription pain medication use and abuse.¹⁶⁰

430. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . [I]t is not even certain that the regulations are helping prevent abuses.¹⁶¹

¹⁵⁹ Institute for Patient Access, *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, (Oct. 2013), http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/01/PT_White-Paper_Final.pdf.

¹⁶⁰ *Id.* at 4-5 (footnote omitted).

¹⁶¹ *Id.* at 5-6.

431. In addition, in an echo of earlier industry efforts to push back against what they termed “opiophobia,” the white paper laments the stigma associated with prescribing and taking pain medication:

Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can’t get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong – or even criminal. ... Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management – a situation fueled by the numerous regulations and fines that surround prescription pain medications.¹⁶²

432. In conclusion, the white paper states that “[p]rescription pain medications, and specifically opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs.”¹⁶³

433. The APA also issues “Patient Access Champion” financial awards to members of Congress, including 50 such awards in 2015. The awards were funded by a \$7.8 million donation from unnamed donors. While the awards are ostensibly given for protecting patients’ access to Medicare and are thus touted by their recipients as demonstrating a commitment to protecting the rights of senior citizens and the middle class, they were generally given to members of Congress who supported the APA’s agenda.¹⁶⁴

434. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the “suspicious orders” provision of the Comprehensive Drug Abuse Prevention and Control Act of

¹⁶² *Id.* at 6.

¹⁶³ *Id.* at 7.

¹⁶⁴ Jaklevic, *Non-profit Alliance for Patient Access*, at 149.

1970, 21 U.S.C. § 801 *et seq.* (“CSA” or “Controlled Substances Act”).¹⁶⁵ The AAPM is also a signatory to this letter. An internal DOJ memo stated that the proposed bill ““could actually result in increased diversion, abuse, and public health and safety consequences””¹⁶⁶ and, according to DEA chief administrative law judge John J. Mulrooney (“Mulrooney”), the law would make it “all but logically impossible” to prosecute manufacturers and distributors, like Defendants here, in the courts.¹⁶⁷ The law passed both Houses of Congress and was signed into law in 2016.

e. The U.S. Pain Foundation

435. The U.S. Pain Foundation (“USPF”) was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. The USPF was one of the largest recipients of contributions from the Marketing Defendants, collecting nearly \$3 million in payments between 2012 and 2015 alone.¹⁶⁸ The USPF was also a critical component of the Marketing Defendants’ lobbying efforts to reduce the limits on over-prescription. The U.S. Pain Foundation advertised its ties to the Marketing Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil (i.e. Janssen), and Mallinckrodt as “Platinum,” “Gold,” and “Basic” corporate members.¹⁶⁹ Industry Front Groups like the American Academy of

¹⁶⁵ Letter from Alliance for Patient Access, et al., to Congressmen Tom Marino, Marsha Blackburn, Peter Welch, and Judy Chu (Jan. 26, 2015).

¹⁶⁶ Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, CBS NEWS (last updated Oct. 17, 2017) <https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/> (hereinafter, “Whitaker, Opioid Crisis Fueled by Drug Industry”).

¹⁶⁷ John J. Mulrooney, II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 Marquette L. Rev. (forthcoming Feb. 2018), <https://www.documentcloud.org/documents/4108121-Marquette-Law-Review-Mulrooney-Legel.html>.

¹⁶⁸ *Fueling an Epidemic*, at p. 4.

¹⁶⁹ *Id.* at 12; U.S. Pain Foundation, *Transparency*, <https://uspainfoundation.org/transparency/>. (last accessed on August 1, 2018).

Pain Management, the American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF.

436. More specifically, Purdue paid \$359,300 from 2012-2017;¹⁷⁰ Janssen paid \$41,500 from 2012-2017;¹⁷¹ and Insys paid \$2,500,000 from 2012-2017 to the USPF.¹⁷²

f. American Geriatrics Society

437. The AGS was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. The AGS was a large recipient of contributions from the Marketing Defendants, including Endo, Purdue and Janssen. AGS contracted with Purdue, Endo, and Janssen to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter “2002 AGS Guidelines”) and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*,¹⁷³ hereinafter “2009 AGS Guidelines”). According to news reports, AGS has received at least \$344,000 in funding from opioid manufacturers since 2009.¹⁷⁴ AGS’s complicity in the common purpose with the Marketing Defendants is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did not want to receive up front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate pro-opioid publications.

¹⁶⁹ *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc'y 1331 (2009), <https://www.ncbi.nlm.nih.gov/pubmed/19573219> (last accessed on August 1, 2018).

¹⁷⁰ *Id.*

¹⁷¹ *Id.*

¹⁷² *Id.*

¹⁷³ *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc'y 1331 (2009), <https://www.ncbi.nlm.nih.gov/pubmed/19573219> (last accessed on August 1, 2018).

¹⁷⁴ John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, MILWAUKEE J. SENTINEL (May 30, 2012), <https://www.medpagetoday.com/geriatrics/painmanagement/32967>.

438. More specifically, Purdue paid \$11,785 from 2012-2017¹⁷⁵ and provided \$40,000 in “corporate roundtable dues” to AGS’s Health in Aging Foundation, a 501(c)(3) organization affiliated with the group between 2012 and 2015.¹⁷⁶

439. The 2009 AGS Guidelines recommended that “[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy.” The panel made “strong recommendations” in this regard despite “low quality of evidence” and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse.¹⁷⁷ These Guidelines further recommended that “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.” These recommendations are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited over 500 times in Google Scholar (which allows users to search scholarly publications that would have been relied on by researchers and prescribers) since their 2009 publication and as recently as this year.

440. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

441. Dr. Bruce Farrell was an AGS task force chairman for the 2009 Guidelines, but was also a paid speaker for Endo, and he helped conduct a CME for treating osteoarthritis pain, which was funded by Purdue.¹⁷⁸

¹⁷⁵ *Fueling an Epidemic Part Two.*

¹⁷⁶ Letter from Nancy E. Lundebjerg, Chief Executive Office, American Geriatrics Society, to Sen. Claire McCaskill (Oct. 11, 2017).

¹⁷⁷ 2009 AGS Guidelines, at 1342.

¹⁷⁸ John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, MILWAUKEE J. SENTINEL (May 30, 2012), <https://www.medpagetoday.com/geriatrics/painmanagement/32967>.

442. Representatives of the Marketing Defendants, often at informal meetings at conferences, suggested activities, lobbying efforts and publications for AGS to pursue. AGS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

443. Members of AGS Board of Directors were doctors who were on the Marketing Defendants' payrolls, either as consultants or as speakers for medical events. As described below, many of the KOLs also served in leadership positions within the AGS.

g. American Chronic Pain Association

444. The Manufacturer Defendants also made substantial payments to the American Chronic Pain Association ("ACPA"). Founded in 1980, the ACPA offers support and education for people suffering with chronic pain.

445. Contributions to the ACPA from the Manufacturing Defendants include \$312,470 from Purdue and \$50,000 from Janssen from 2012-2017.¹⁷⁹ Between 2013 and 2016, 10 members of ACPA's Advisory Board received more than \$140,000 from opioid manufacturers, including Endo.

4. The Marketing Defendants Deceptively Paid Key Opinion Leaders to Promote Opioid Use

446. To falsely promote their opioids, the Marketing Defendants paid and cultivated a select circle of doctors who were chosen and sponsored by the Marketing Defendants for their supportive messages. As set forth below, pro-opioid doctors have been at the hub of the Marketing Defendants' well-funded, pervasive marketing scheme since its inception and were used to create the grave misperception that science and legitimate medical professionals favored the wider and broader use of opioids. These doctors include Dr. Russell Portenoy, Dr. Lynn Webster, Dr. Perry

¹⁷⁹ *Fueling an Epidemic Part Two.*

Fine, and Dr. Scott Fishman.

447. Although these KOLs were funded by the Marketing Defendants, the KOLs were used extensively to present the appearance that unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain had been conducted and was being reported on by independent medical professionals.

448. As the Marketing Defendants' false marketing scheme picked up steam, these pro-opioid KOLs wrote, consulted on, edited, and lent their names to books and articles, and gave speeches and CMEs supportive of opioid therapy for chronic pain. They served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and they were placed on boards of pro-opioid advocacy groups and professional societies that developed, selected, and presented CMEs.

449. Through use of their KOLs and strategic placement of these KOLs throughout every critical distribution channel of information within the medical community, the Marketing Defendants were able to exert control of each of these modalities through which doctors receive their information.

450. In return for their pro-opioid advocacy, the Marketing Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish. For example, Dr. Webster has received funding from Endo, Purdue, and Cephalon. Dr. Fine has received funding from Janssen, Cephalon, Endo, and Purdue.

451. The Marketing Defendants carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of the Marketing Defendants' agenda. The Marketing Defendants also kept close tabs on the content of the materials published by these KOLs. Of course, the Marketing Defendants also kept these KOLs well funded, enabling them to push the Marketing

Defendants' deceptive message out to the medical community.

452. Once the Marketing Defendants identified and funded KOLs and those KOLs began to publish "scientific" papers supporting the Marketing Defendants' false position that opioids were safe and effective for treatment of chronic pain, the Marketing Defendants poured significant funds and resources into a marketing machine that widely cited and promoted their KOLs and studies or articles by their KOLs to drive prescriptions of opioids for chronic pain. The Marketing Defendants cited to, distributed, and marketed these studies and articles by their KOLs as if they were independent medical literature so that it would be well-received by the medical community. By contrast, the Marketing Defendants did not support, acknowledge, or disseminate the truly independent publications of doctors critical of the use of chronic opioid therapy.

453. In their promotion of the use of opioids to treat chronic pain, the Marketing Defendants' KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth in doing so, but they continued to publish their misstatements to benefit themselves and the Marketing Defendants.

a. Dr. Russell Portenoy

454. In 1986, Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while at the same time serving as a top spokesperson for drug companies, published an article reporting that "[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy."¹⁸⁰

455. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

¹⁸⁰ Russell Portenoy & Kathy Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, 25(2) Pain 171 (1986), <https://www.ncbi.nlm.nih.gov/pubmed/2873550>.

The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. *Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.*¹⁸¹

(emphasis added). According to Dr. Portenoy, the foregoing problems could constitute “compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain.”¹⁸²

456. Despite having taken this position on long-term opioid treatment, Dr. Portenoy ended up becoming a spokesperson for Purdue and other Marketing Defendants, promoting the use of prescription opioids and minimizing their risks. A respected leader in the field of pain treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, described him “lecturing around the country as a religious-like figure. The megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak. It was a compelling message: ‘Docs have been letting patients suffer; nobody really gets addicted; it’s been studied.’”¹⁸³

¹⁸¹ Russell Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994) (emphasis added).

¹⁸² *Id.*

¹⁸³ *Dreamland* at 314.

457. As one organizer of CME seminars who worked with Portenoy and Purdue pointed out, “had Portenoy not had Purdue’s money behind him, he would have published some papers, made some speeches, and his influence would have been minor. With Purdue’s millions behind him, his message, which dovetailed with their marketing plans, was hugely magnified.”¹⁸⁴

458. Dr. Portenoy was also a critical component of the Marketing Defendants’ control over their Front Groups. Specifically, Dr. Portenoy sat as a Director on the board of the APF. He was also the President of the APS.

459. In recent years, some of the Marketing Defendants’ KOLs have conceded that many of their past claims in support of opioid use lacked evidence or support in the scientific literature.¹⁸⁵ Dr. Portenoy has now admitted that he minimized the risks of opioids,¹⁸⁶ and that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true.”¹⁸⁷ He mused, “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did . . .”¹⁸⁸

460. In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work purposefully relied on evidence that was not “real” and left real evidence behind:

I gave so many lectures to primary care audiences in which the Porter and Jick

¹⁸⁴ *Id.* at 136.

¹⁸⁵ See, e.g., John Fauber, *Painkiller boom fueled by networking*, Journal Sentinel (Feb. 18, 2012), <http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html> (reporting that a key Endo KOL acknowledged that opioid marketing went too far).

¹⁸⁶ Celine Gounder, *Who Is Responsible for the Pain-Pill Epidemic?*, THE NEW YORKER (Nov. 8, 2013), <https://www.newyorker.com/business/currency/who-is-responsible-for-the-pain-pill-epidemic> (hereinafter “Gounder, *Who Is Responsible*”).

¹⁸⁷ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, THE WALL STREET JOURNAL (Dec. 17, 2012), <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

¹⁸⁸ *Id.*

article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, *none of which represented real evidence*, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn't before. *In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind.*¹⁸⁹

461. Several years earlier, when interviewed by journalist Barry Meier for his 2003 book, *Pain Killer*, Dr. Portenoy was more direct: "It was pseudoscience. I guess I'm going to have always to live with that one."¹⁹⁰

b. Dr. Lynn Webster

462. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a Front Group that ardently supports chronic opioid therapy. He is a Senior Editor of Pain Medicine, the same journal that published Endo's special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly \$2 million from Cephalon).

463. Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported

¹⁸⁹ Harrison Jacobs, *This one-paragraph letter may have launched the opioid epidemic*, BUSINESS INSIDER (May 26, 2016), <http://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid-epidemic-2016-5>; Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YOUTUBE (Oct. 30, 2011), <https://www.youtube.com/watch?v=DgyuBWN9D4w&feature=youtu.be>.

¹⁹⁰ *Pain Killer*, at 277.

guidelines. Versions of Dr. Webster's Opioid Risk Tool ("ORT") appear on, or are linked to, websites run by Endo, Janssen, and Purdue. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors at hospitals such as Plaintiffs.

464. Dr. Webster was himself tied to numerous overdose deaths. He and the Lifetree Clinic were investigated by the DEA for overprescribing opioids after twenty patients died from overdoses. In keeping with the Marketing Defendants' promotional messages, Dr. Webster apparently believed the solution to patients' tolerance or addictive behaviors was more opioids: he prescribed staggering quantities of pills.

465. At an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Webster and others titled, "Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results." The presentation's agenda description states: "Most patients with chronic pain experience episodes of breakthrough pain, yet no currently available pharmacologic agent is ideal for its treatment." The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the "[i]nterim results of this study suggest that [fentanyl buccal] is safe and well-tolerated in patients with chronic pain and [breakthrough pain]." This CME effectively amounted to off-label promotion of Cephalon's opioids, even though they were approved only for cancer pain.

466. Cephalon sponsored a CME written by Dr. Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007 through December

15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

c. Dr. Perry Fine

467. Dr. Perry Fine's ties to the Marketing Defendants have been well documented. He has authored articles and testified in court cases and before state and federal committees, and he, too, has argued against legislation restricting high-dose opioid prescription for non-cancer patients. He has served on Purdue's advisory board, provided medical legal consulting for Janssen, and participated in CME activities for Endo, along with serving in these capacities for several other drug companies. He co-chaired the APS-AAPM Opioid Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was also on the board of directors of APF.¹⁹¹

468. Multiple videos feature Fine delivering educational talks about prescription opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity Anna Nicole Smith before her death for pain did not make her an addict.

469. Dr. Fine has also acknowledged having failed to disclose numerous conflicts of interest. For example, Dr. Fine failed to fully disclose payments received as required by his employer, the University of Utah—telling the university that he had received under \$5,000 in 2010 from Johnson & Johnson for providing “educational” services, but Johnson & Johnson’s website states that the company paid him \$32,017 that year for consulting, promotional talks, meals and

¹⁹¹ Scott M. Fishman, MD, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306 (13) JAMA 1445 (Sept. 20, 2011), <https://jamanetwork.com/journals/jama/article-abstract/1104464?redirect=true>.

travel.¹⁹²

470. Dr. Fine and Dr. Portenoy co-wrote *A Clinical Guide to Opioid Analgesia* in which they downplayed the risks of opioid treatment such as respiratory depression and addiction:

At clinically appropriate doses . . . respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk.

Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare among patients who receive opioids for a short period (i.e., for acute pain) and among those with no history of abuse who receive long-term therapy for medical indications.¹⁹³

471. In November 2010, Dr. Fine and others published an article presenting the results of another Cephalon-sponsored study titled “Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study.”¹⁹⁴ In that article, Dr. Fine explained that the 18-month “open-label” study “assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for non-cancer pain.”¹⁹⁵ The article acknowledged that: (a) “[t]here has been a steady increase in the use of opioids for the management of chronic non-cancer pain over the past two decades”; (b) the “widespread acceptance” had led to the publishing of practice guidelines “to provide evidence-and consensus-based recommendations for the optimal use of opioids in the management of

¹⁹² Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011), <https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry>.

¹⁹³ Perry G. Fine, MD & Russell K. Portenoy, MD, *A Clinical Guide to Opioid Analgesia* 20 and 34, McGraw-Hill Companies (2004), <http://www.thblack.com/links/RSD/OpioidHandbook.pdf>.

¹⁹⁴ Perry G. Fine, et al., *Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study*, 40(5) J. Pain & Symptom Management 747-60 (Nov. 2010).

¹⁹⁵ *Id.*

chronic pain”; and (c) those guidelines lacked “data assessing the long-term benefits and harms of opioid therapy for chronic pain.”¹⁹⁶

472. The article concluded: “[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable.” They also conclude that the number of abuse-related events was “small.”¹⁹⁷

473. Multiple videos feature Dr. Fine delivering educational talks about the drugs. In one video from 2011 titled “Optimizing Opioid Therapy,” he sets forth a “Guideline for Chronic Opioid Therapy” discussing “opioid rotation” (switching from one opioid to another) not only for cancer patients, but also for non-cancer patients, and suggests it may take four or five switches over a person’s “lifetime” to manage pain.¹⁹⁸ He states the “goal is to improve effectiveness which is different from efficacy and safety.” Rather, for chronic pain patients, effectiveness “is a balance of therapeutic good and adverse events *over the course of years.*”¹⁹⁹ The entire program assumes that opioids are appropriate treatment over a “protracted period of time” and even over a patient’s entire “lifetime.” He even suggests that opioids can be used to treat *sleep apnea*. He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with “tools,” but leaves that for “a whole other lecture.”²⁰⁰

d. Dr. Scott Fishman

474. Dr. Scott Fishman is a physician whose ties to the opioid drug industry are multitudinous. He has served as an APF board member and as president of the AAPM and has

¹⁹⁶ *Id.*

¹⁹⁷ *Id.*

¹⁹⁸ Perry A. Fine, M.D., *Safe and Effective Opioid Rotation*, YOUTUBE (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI.

¹⁹⁹ *Id.*

²⁰⁰ *Id.*

participated yearly in numerous CME activities for which he received “market rate honoraria.” As discussed below, he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Marketing Defendants. He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in the *Journal of the American Medical Association* titled “Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion.”²⁰¹

475. Dr. Fishman authored a physician’s guide on the use of opioids to treat chronic pain titled “Responsible Opioid Prescribing,” in 2007, which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain.

476. In 2012, Dr. Fishman updated the guide and continued emphasizing the “catastrophic” “under-treatment” of pain and the “crisis” such under-treatment created:

Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, it’s critical to remember that the problem of unrelieved pain remains as urgent as ever.²⁰²

477. The updated guide still assures that “[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins.”²⁰³

²⁰¹ Scott M. Fishman, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306(13) JAMA 1445 (2011); Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011), <https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry> (hereinafter “Weber, Two Leaders in Pain”).

²⁰² Scott M. Fishman, *Responsible Opioid Prescribing: A Guide for Michigan Clinicians*, 10-11 (Waterford Life Sciences 2012).

²⁰³ *Id.*

478. In another guide by Dr. Fishman, he continues to downplay the risk of addiction: “I believe clinicians must be very careful with the label ‘addict.’ I draw a distinction between a ‘chemical coper’ and an addict.”²⁰⁴ The guide also continues to present symptoms of addiction as symptoms of “pseudoaddiction.”

5. The Marketing Defendants Also Spread Their Misleading Messages to Reputable Organizations

479. The Manufacturing Defendants also manipulated reputable organizations like the Joint Commission on Accreditation of Healthcare Organizations (the “Joint Commission”) in order to further advance their unlawful marketing of opioids. The Joint Commission certifies over 21,000 health care organizations and is the nation’s oldest and largest standards-setting and accrediting body in health care.²⁰⁵

480. In 2000, Purdue sponsored a book through the Joint Commission which claimed “there is no evidence that addiction is a significant issue when persons are given opioids for pain control.”²⁰⁶ It also called doctors’ concerns about addiction side effects “inaccurate and exaggerated.”²⁰⁷ Dr. David W. Baker, the Joint Commission’s executive vice president for health care quality evaluation, has acknowledged that “[t]he Joint Commission was one of the dozens of individual authors and organizations that developed educational materials for pain management that propagated this erroneous information.”²⁰⁸

²⁰⁴ Scott M. Fishman, *Listening to Pain: A Physician’s Guide to Improving Pain Management Through Better Communication* 45 (Oxford University Press 2012).

²⁰⁵ Joint Commission, *FAQ Page*, available at <https://www.jointcommission.org/about/jointcommissionfaqs.aspx?CategoryId=10#2274> (last accessed August 1, 2018).

²⁰⁶ Sonia Moghe, *Opioid history: From ‘wonder drug’ to abuse epidemic*, CNN (Oct. 13, 2016), <https://www.cnn.com/2016/05/12/health/opioid-addiction-history/>.

²⁰⁷ *Id.*

²⁰⁸ *Id.*

481. In 2001, due to the influence of the Marketing Defendants, the Joint Commission, along with the National Pharmaceutical Council (founded in 1953 and supported by the nation's major research-based biopharmaceutical companies²⁰⁹) "introduced standards for [hospitals] to improve their care for patients with pain." The new standards for hospitals put patient pain front and center as the "fifth vital sign." This monograph, entitled *Pain: Current Understanding of Assessment, Management and Treatments* required assessment of pain in all patients.

482. The Joint Commission's first pain management standards placed responsibility for pain control on health care organizations (hospitals), and emphasized the need for hospitals to do systematic assessments and use quantitative measures of pain which was consistent with the position of the Front Group APS.

483. As a result of the Marketing Defendants' efforts to manipulate the standard of care, many hospitals, including Plaintiffs, risked loss of their Joint Commission accreditation if they did not incorporate the "fifth vital sign" standard and put pain at the forefront of their treatment. For example, the emergency department at Oconomowoc Memorial Hospital in Wisconsin achieved 10 consecutive years of patient satisfaction in the 99th percentile, a feat no other emergency hospital in the United States has been able to accomplish.²¹⁰ However, during its routine Joint Commission survey, The Joint Commission found that the hospital was not adequately documenting follow up questions after prescribing pain medications to patients.²¹¹ As a result, the hospital was given only one quarter to bring their compliance up to 90%.²¹² They could not, and as a result their Joint Commission accreditation was at risk for the entire hospital.²¹³ Loss of

²⁰⁹ Currently funded by Johnson & Johnson, Purdue and Teva, among others.

²¹⁰ Westlake testimony, at 6.

²¹¹ *Id.*

²¹² *Id.*

²¹³ *Id.*

accreditation by The Joint Commission can result in the loss of a huge amount of hospital resources to become reaccredited, despite having a patient satisfaction rating of 99% for the same period.²¹⁴

484. Since 2001, The Joint Commission standards relating to pain assessment and management have been revised to lessen emphasis on pain. However, the damage caused by the Marketing Defendants' marketing campaigns could not be undone. Dr. Baker explains that "the concept that iatrogenic addiction was rare and that long acting opioids were less addictive had been greatly reinforced and widely repeated, and studies refuting these claims were not published until several years later."

6. The Marketing Defendants Disseminated Their Misrepresentations Through Continuing Medical Education Programs

485. Now that the Marketing Defendants had both a group of physician promoters and had built a false body of "literature," Defendants needed to make sure their false marketing message was widely distributed.

486. One way the Marketing Defendants aggressively distributed their false message was through countless CME programs.

487. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are generally delivered in person, often in connection with professional organizations' conferences, online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but also to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs typically are taught by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

²¹⁴ *Id.*

488. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Defendants aimed to reach general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to the Marketing Defendants' deceptions.

489. The Marketing Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focused on opioids to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

490. Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape, LLC ("Medscape") and which disseminated false and misleading information to physicians across the country.

491. Another Cephalon-sponsored CME presentation titled *Breakthrough Pain: Treatment Rationale with Opioids* was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor who "previously operated back, complex pain syndromes, the neuropathies, and interstitial cystitis." He describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using "targeted pharmacotherapeutics to affect multiple points in the pain-signaling pathway."²¹⁵ The doctor lists fentanyl as one of the most effective opioids available for treating breakthrough pain, describing its use as

²¹⁵ Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale With Opioids*, Medscape, <http://www.medscape.org/viewarticle/461612> (last accessed August 1, 2018).

an expected and normal part of the pain management process.²¹⁶ Nowhere in the CME is cancer or cancer-related pain even mentioned, despite FDA restrictions that fentanyl use be limited to cancer-related pain.

492. Teva paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that “clinically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility” and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

493. *Responsible Opioid Prescribing* was sponsored by Purdue, Endo and Teva. The FSMB website described it as the “leading continuing medical education (CME) activity for prescribers of opioid medications.” Endo sales representatives distributed copies of *Responsible Opioid Prescribing* with a special introductory letter from Dr. Scott Fishman.

494. In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally.

495. The American Medical Association (“AMA”) recognized the impropriety that pharmaceutical company-funded CMEs create, stating that support from drug companies with a financial interest in the content being promoted “creates conditions in which external interests could influence the availability and/or content” of the programs and urged that “[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter.”²¹⁷

²¹⁶ *Id.*

²¹⁷ Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass’n (Nov. 2011).

496. Physicians attended or reviewed CMEs sponsored by the Marketing Defendants during the relevant time period and were misled by them.

497. By sponsoring CME programs put on by Front Groups like APF, AAPM, and others, the Marketing Defendants expected and understood that instructors would deliver messages favorable to them, as these organizations were dependent on the Marketing Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Marketing Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and the Marketing Defendants both measure the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

7. The Marketing Defendants Used "Branded" Advertising to Promote Their Products to Doctors and Consumers

498. The Marketing Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs. The Marketing Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the Journal of Pain and Clinical Journal of Pain, to journals with wider medical audiences, such as the Journal of the American Medical Association. The Marketing Defendants collectively spent more than \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. The 2011 total includes \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.

499. The Marketing Defendants also targeted consumers in their advertising. They knew that physicians are more likely to prescribe a drug if a patient specifically requests it.²¹⁸ They also

²¹⁸ In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. J.B. McKinlay et al.,

knew that this willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved.²¹⁹ Endo’s research, for example, found that such communications resulted in greater patient “brand loyalty,” with longer durations of Opana ER therapy and fewer discontinuations. The Marketing Defendants thus increasingly took their opioid sales campaigns directly to consumers, including through patient-focused “education and support” materials in the form of pamphlets, videos, or other publications that patients could view in their physician’s office.

8. The Marketing Defendants Used “Unbranded” Advertising to Promote Opioid Use for Chronic Pain Without FDA Review

500. The Marketing Defendants also aggressively promoted opioids through “unbranded advertising” to generally tout the benefits of opioids without specifically naming a particular brand-name opioid drug. Instead, unbranded advertising is usually framed as “disease awareness”—encouraging consumers to “talk to your doctor” about a certain health condition without promoting a specific product and, therefore, without providing balanced disclosures about the product’s limits and risks. In contrast, a pharmaceutical company’s “branded” advertisement that identifies a specific medication and its indication (i.e., the condition which the drug is approved to treat) must also include possible side effects and contraindications—what the FDA Guidance on pharmaceutical advertising refers to as “fair balance.” Branded advertising is also subject to FDA review for consistency with the drug’s FDA-approved label. Through unbranded materials, the Marketing Defendants expanded the overall acceptance of and demand for chronic opioid therapy without the restrictions imposed by regulations on branded advertising.

Effects of Patient Medication Requests on Physician Prescribing Behavior, 52(2) Med. Care 294 (2014).

²¹⁹ *Id.*

501. Many of the Marketing Defendants utilized unbranded websites to promote opioid use without promoting a specific branded drug, such as Purdue’s pain-management website, www.inthefaceofpain.com. The website contained testimonials from several dozen “advocates,” including health care providers, urging more pain treatment. The website presented the advocates as neutral and unbiased, but an investigation by the New York Attorney General later revealed that Purdue paid the advocates hundreds of thousands of dollars.

9. The Marketing Defendants Funded, Edited and Distributed Publications That Supported Their Misrepresentations

502. The Marketing Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was calculated to shape the perceptions of prescribers, patients, and payors. This literature served marketing goals, rather than scientific standards, and was intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

503. To accomplish their goal, the Marketing Defendants—sometimes through third-party consultants and/or Front Groups—commissioned, edited, and arranged for the placement of favorable articles in academic journals.

504. The Marketing Defendants’ plans for these materials did not originate in the departments with the organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients; rather, they originated in the Marketing Defendants’ marketing departments.

505. The Marketing Defendants made sure that favorable articles were disseminated and cited widely in the medical literature, even when the Marketing Defendants knew that the articles distorted the significance or meaning of the underlying study, as with the Porter & Jick letter. The

Marketing Defendants also frequently relied on unpublished data or posters, neither of which are subject to peer review, but were presented as valid scientific evidence.

506. The Marketing Defendants published or commissioned deceptive review articles, letters to the editor, commentaries, case-study reports, and newsletters aimed at discrediting or suppressing negative information that contradicted their claims or raised concerns about chronic opioid therapy.

507. For example, in 2007 Cephalon sponsored the publication of an article titled “*Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Non-cancer Pain: Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate*,”²²⁰ published in the nationally circulated Journal of Pain Medicine, to support its effort to expand the use of its branded fentanyl products. The article’s authors (including Dr. Lynn Webster, discussed above) stated that the “OTFC [fentanyl] has been shown to relieve BTP [breakthrough pain] more rapidly than conventional oral, normal-release, or ‘short acting’ opioids” and that “[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality of life] of non-cancer pain patients.” The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Portenoy and recommends fentanyl for non-cancer BTP patients:

In summary, BTP appears to be a clinically important condition in patients with chronic non-cancer pain and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP and the potential benefits of BTP-specific therapy suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools.²²¹

²²⁰ Donald R. Taylor, et al., *Impact of Breakthrough Pain on Quality of Life in Patients With Chronic, Non-cancer Pain: Patient Perceptions and Effect of Treatment With Oral Transmucosal Fentanyl Citrate (OTFC, ACTIQ)*, 8(3) Pain Med. 281-88 (Mar. 2007).

²²¹ *Id.*

10. The Marketing Defendants Used Speakers' Bureaus and Programs to Spread Their Deceptive Messages.

508. In addition to making sales calls, the Marketing Defendants' detailers also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers with meals paid for by the Marketing Defendants. These speaker programs and associated speaker trainings served three purposes: they provided 1) an incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; 2) an opportunity for doctors to be selected to attend forum at which the drug companies could further market to the speaker himself or herself; and 3) an opportunity for the doctors to market to their peers. The Marketing Defendants graded their speakers, and future opportunities were based on speaking performance, post-program sales, and product usage. Purdue, Janssen, Endo, Cephalon, and Mallinckrodt each made thousands of payments to physicians nationwide, for activities including participating on speakers' bureaus, providing consulting services, and other services.

509. As detailed below, Insys paid prescribers for *fake* speakers' programs in exchange for prescribing its product, Subsys. Insys's schemes resulted in countless speakers' programs at which the designated speaker did not speak, and, on many occasions, speaker programs at which the only attendees at the events were the speaker and an Insys sales representative. It was a pay-to-prescribe program. Insys used speakers' programs as a front to pay for prescriptions, and paid to push opioids onto patients who did not need them.

C. The Marketing Defendants' Goal Was for More Patients to Take More Opioids at Higher Doses for Longer Periods of Time

1. Increasing the Patient Population

a. The Marketing Defendants Focused on Vulnerable Populations

510. The Marketing Defendants specifically targeted their marketing at two particularly vulnerable populations—the elderly and veterans – who tend to suffer from chronic pain.

i. Elderly Patients

511. Internal Purdue documents demonstrate that the Purdue Individual Defendants focused on elderly patients because they are frequent pain sufferers, and, of equal importance, are likely to be covered by Medicare. Purdue internal documents reflected that if it targeted “Patients over the age of 65 … more Medicare Part D coverage is achieved.”

512. Elderly patients frequently suffer from osteoarthritis, but opioids are not approved to treat the condition. Purdue conducted a single study on osteoarthritis for its Butrans opioid, and it failed. Purdue admitted in internal documents that its opioids “are not indicated for a specific disease” and “it is very important that you never suggest to your HCP [health care professional] that OxyContin is indicated for the treatment of a specific disease state such as Rheumatoid Arthritis or Osteoarthritis.” Nevertheless, to meet its business goals, Purdue trained its representatives to mislead doctors by promoting opioids for osteoarthritis without disclosing Purdue’s failed trial. Purdue even measured how often it targeted osteoarthritis patients. A Purdue marketing presentation concluded that its sales reps were “identifying appropriate patients” because osteoarthritis was specifically mentioned during 35% of sales visits. Purdue also directed sales reps to use marketing materials that highlight patients with osteoarthritis, even though Purdue drugs were never indicated for that disease and Purdue’s Butrans trial had failed. At one point, the Purdue Board wanted to know if sales reps could sell more by remaining silent about the failed trial: “What can be said in response to a prescriber who asks directly or indirectly, ‘can this product be prescribed for my patient with OA?’ In responding are we required to specifically mention the failed trials in OA?”

513. The Marketing Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline

observes that existing evidence confirms that elderly patients taking opioids suffer from elevated fall and fracture risks, reduced renal function and medication clearance, and a smaller window between safe and unsafe dosages.²²² Elderly patients taking opioids have also been found to have a greater risk for hospitalizations and increased vulnerability to adverse drug effects and interactions, such as respiratory depression. The 2016 CDC Guideline concludes that there must be “additional caution and increased monitoring” to minimize the risks of opioid use in elderly patients.²²³

ii. Veterans

514. According to a study published in the 2013 Journal of American Medicine, veterans returning from Iraq and Afghanistan who were prescribed opioids have a higher incidence of adverse clinical outcomes, such as overdoses and self-inflicted and accidental injuries. A 2008 survey showed that prescription drug misuse among military personnel doubled from 2002 to 2005, and then nearly tripled again over the next three years. Veterans are twice as likely as non-veterans to die from an opioid overdose.

515. Yet the Marketing Defendants deliberately targeted veterans with deceptive marketing. For example, a 2009 publication sponsored by Purdue, Endo, and Janssen, and distributed by APF with grants from Janssen and Endo, was written as a personal narrative of one veteran but was in fact another vehicle for opioid promotion. Called *Exit Wounds*, the publication describes opioids as “underused” and the “gold standard of pain medications” while failing to disclose significant risks of opioid use, including the risks of fatal interactions with benzodiazepines. According to a VA Office of Inspector General Report, 92.6% of veterans who

²²² 2016 CDC Guideline.

²²³ *Id.* at 27.

were prescribed opioid drugs were also prescribed benzodiazepines, despite the increased danger of respiratory depression from combining the two drugs.

516. Opioid prescriptions have dramatically increased for veterans and the elderly. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59. And in 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills—four times as many as they did in 2001.

b. The Marketing Defendants Focused on Having Opioids Perceived as a “First Line” of Medication for “Opioid-Naïve” Patients, Rather Than as a Last Resort for Cancer Patients and the Terminally Ill

517. From the very beginning, Purdue and Abbott intended to position OxyContin as useful for more than just cancer pain. Internal documents from the 1995 “OxyContin Launch” indicate they also intended it for a “secondary market … for non-malignant pain (musculoskeletal, injury and trauma)” and that it must be “reinforced that we do not want to niche OxyContin just for cancer pain.”

518. In 1996, Purdue envisioned OxyContin being prescribed for a long laundry list of conditions, and literally generated a “wish list” of clinical studies to support its prescription in a variety of contexts, including: (1) postoperative pain, with specific objectives of supporting the “Abbott agreement” to market to hospitals, removing “the prohibition of giving the product during the 12-24 hour immediate postop period,” and removing “the qualification limiting the indication to pain for more than a few days,” (2) “nonmalignant pain” (including low back pain, osteoarthritis), (3) HIV/AIDS treatment.

519. Purdue, particularly after its overall OxyContin sales began to slow after 2010, instructed its sales representatives to focus on expanding the patient base, by promoting its drugs

specifically for patients who had not previously taken opioids, who it described as “opioid-naïve” or simply “naïve” patients:

- *“Your opportunity here is with the naive community, let’s use the naive trial to make your case.”*
- *“You created an epiphany with the doctor today (potentially) by reviewing the opiate naive patient profile. What made him more pat to write for this patient, being an amiable doctor, is the fact that he would not have to talk patients out of their short acting [opioids].”*
- *“This was an example of what a good call looks like ... [Dr.] was particularly interested in the RM case study of Marjorie, which generated a robust discussion of opioid naive patients ...”*

520. Purdue also promoted its drugs for opioid-naïve patients using the deceptive term “first line opioid.” “First line” is a medical term for the preferred first step in treating a patient. Opioids are not an appropriate first line therapy. Nevertheless, Purdue’s internal documents and testimony from sales representatives shows that Purdue repeatedly promoted OxyContin as “first line” — “the first thing they would take to treat pain.”

521. A particularly insidious aspect of Purdue’s focus on “naïve” patients, and on keeping patients on opioids longer, was its savings card program. The cards provided a discount on a patient’s first five prescriptions. In 2012, Purdue’s internal 10-year plan highlighted its discovery that opioid savings cards kept patients on opioids longer: “more patients remain on OxyContin after 90 days. The savings card program was incredibly lucrative -- the return on investment for Purdue was 4.28, so that every \$1,000,000 Purdue gave away in savings came back to Purdue as \$4,280,000 in revenue because patients stayed on dangerous opioids longer. Discounts could have cut Purdue’s revenue *if* patients took opioids for a short time. But Purdue’s internal 10-year plan highlighted its discovery that opioid savings cards kept patients on opioids longer: “more patients remain on OxyContin after 90 days.”

522. Purdue sales representatives did not disclose to doctors that opioid naïve patients faced greater risks of overdose and death. Purdue focused on less sophisticated prescribers, such as its “core” prolific prescribers, and certain nurses and physician assistants who might be more vulnerable to persuasion by its sales representatives.

2. Increasing Dosages and Increasing Them Quickly to Keep Patients on Longer

523. In order to promote long-term sales, the Marketing Defendants promoted the prescription of higher dosages of opioids. There were several dimensions to this. First, the Marketing Defendants charged more for the higher dosages. More importantly, patients who took higher dosages would stay on opioids longer.

524. At Purdue, staff, from sales representatives to senior management including the Purdue Individual Defendants, regularly and candidly discussed internally the imperative of increasing prescribed dosages. Accordingly, Purdue’s second most important sales tactic (after frequent sales representative visits, the most important strategy employed by Purdue) was to cause prescribers to prescribe higher doses. This was manifested in Purdue’s *Individualize the Dose* campaign, and was communicated to prescribers in sales representatives’ visits. Sales representatives were relentlessly pressured to increase the average doses prescribed by the prescribers in their territories. An aspect of this strategy was to encourage faster upward *titration*, that is moving quickly from smaller to larger doses. The lowest dosage of Purdue’s Butrans product, for example, was described to prescribers as an “introductory” dose that would presumptively be increased for most if not all patients.

525. Purdue secretly determined that pushing patients to higher doses would keep them on opioids longer. Purdue developed tactics specifically to keep patients hooked on opioids longer, which it called by the euphemism: “*Improving the Length of Therapy*” — sometimes abbreviated

as “LOT” or “LoT.” Purdue taught its employees that there is “a direct relationship” between getting patients on higher doses and keeping them on Purdue’s opioids longer.

526. The Marketing Defendants’ focus on increasing dosages, and increasing the duration of opioid usage, had devastating consequences for patients. Patients exposed to higher dosages, and for longer periods of time, are many times more likely to become addicted, and to overdose.

D. The Marketing Defendants’ Scheme Succeeded, Creating a Public Health Epidemic

1. The Marketing Defendants Dramatically Expanded Opioid Prescribing and Use

527. The Marketing Defendants necessarily expected a return on the enormous investment they made in their deceptive marketing scheme, and they worked to measure and expand their success. Their own documents show that they knew they were influencing prescribers and increasing prescriptions. Studies also show that in doing so, they fueled an epidemic of addiction and abuse.

528. Cephalon recognized the return of its efforts to market Actiq and Fentora off-label for chronic pain. In 2000, Actiq generated \$15 million in sales. By 2002, Actiq sales had increased by 92%, which Cephalon attributed to “a dedicated sales force for ACTIQ” and “ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists.”²²⁴ Actiq became Cephalon’s second best-selling drug. By the end of 2006, Actiq’s sales had exceeded \$500 million.²²⁵ Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by

²²⁴ Cephalon, Inc. Annual Report (Form 10-K) at 28 (Mar. 31, 2003), <https://www.sec.gov/Archives/edgar/data/873364/000104746903011137/a2105971z10-k.htm>.

²²⁵ Carreyrou, *Narcotic Lollipop*.

oncologists. One measure suggested that “more than 80 percent of patients who use[d] the drug don’t have cancer.”²²⁶

529. Each of the Marketing Defendants tracked the impact of their marketing efforts to measure their impact in changing doctors’ perceptions and prescribing of their drugs. They purchased prescribing and survey data that allowed them to closely monitor these trends, and they did actively monitor them. For instance, they monitored doctors’ prescribing before and after detailing visits and before and after speaker programs. Defendants continued and, in many cases, expanded and refined their aggressive and deceptive marketing for one reason: it worked. As described in this Complaint, both in specific instances (e.g., the low abuse potential of various Defendants’ opioids), and more generally, Defendants’ marketing changed prescribers’ willingness to prescribe opioids, led them to prescribe more of their opioids, and persuaded them not to stop prescribing opioids or to switch to “safer” opioids, such as ADF.

530. This success would have come as no surprise. Drug company marketing materially impacts doctors’ prescribing behavior.²²⁷ The effects of sales calls on prescribers’ behavior is well documented in the literature. One study examined four practices, including visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on drug utilization. An additional study

²²⁶*Id.*

²²⁷ See, e.g., P. Manchanda & P. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); I. Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs); see also A. Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue’s sales force and trebling of annual sales calls).

found that doctor meetings with sales representatives are related to changes in both prescribing practices and requests by physicians to add the drugs to hospitals' formularies.

531. Marketing Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain.²²⁸ These results are directly due to the Marketing Defendants' fraudulent marketing campaign focused on several misrepresentations.

532. Thus, both independent studies and Defendants' own tracking confirm that Defendants' marketing scheme dramatically increased their sales.

2. The Marketing Defendants' Deception in Expanding Their Market Created and Fueled the Opioid Epidemic.

533. Independent research demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."²²⁹ It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions.

²²⁸ CS Hwang et al., *Prescription Drug Abuse: A National Survey of Primary Care Physicians*, 175 JAMA Intern. Med. 302 (2014), doi: 10.1001/jamainternmed.2014.6520, <https://www.ncbi.nlm.nih.gov/pubmed/25485657>.

²²⁹ Theodore J. Cicero et al., *Relationship Between Therapeutic Use and Abuse of Opioid Analgesics in Rural, Suburban, and Urban Locations in the United States*, 16 *Pharmacoepidemiology and Drug Safety*, 827-40 (2007), doi: 10.1002/pds.1452, <https://www.cdhs.udel.edu/content-sub-site/Documents/Publications/Relationship%20Between%20Therapeutic%20Use%20and%20Abuse%20of%20Opioid%20Analgesics.pdf>.

534. There is a “parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes.” The opioid epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”²³⁰

535. In a 2016 report, the CDC explained that “[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses.” Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”

E. Each of the Marketing Defendants Made Materially Deceptive Statements and Concealed Material Facts

536. As alleged herein, the Marketing Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts in the course of manufacturing, marketing, and selling prescription opioids. The Marketing Defendants’ actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

537. As a part of their deceptive marketing scheme, the Marketing Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the United States. For example, the Marketing Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept the Marketing Defendants’ misrepresentations.

²³⁰ See Califf, et al.

1. Purdue

538. Defendant Purdue made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- c. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;
- d. Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- e. Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- p. Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- q. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing; and
- r. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

539. More specifically, Defendant Purdue made and/or disseminated deceptive statements, and promoted a culture that mislead doctors and patients into believing opioids were safe for chronic care, including, but not limited to, the following:

- a. In 1998, Purdue distributed 15,000 copies of an OxyContin video to physicians without submitting it to the FDA for review, an oversight

later acknowledged by Purdue. In 2001, Purdue submitted to the FDA a second version of the video, which the FDA did not review until October 2002—after the General Accounting Office inquired about its content. After its review, the FDA concluded that the video minimized the risks from OxyContin and made unsubstantiated claims regarding its benefits to patients.²³¹

- b. According to training materials, Purdue instructed sales representatives to assure doctors—repeatedly and without evidence—that “fewer than one per cent” of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen per cent.)²³²
- c. Andrew Kolodny, the co-director of the Opioid Policy Research Collaborative, at Brandeis University, has worked with hundreds of patients addicted to opioids. He has stated that, though many fatal overdoses have resulted from opioids other than OxyContin, the crisis was initially precipitated by a shift in the culture of prescribing—a shift carefully engineered by Purdue. “If you look at the prescribing trends for all the different opioids, it’s in 1996 that prescribing really takes off,” Kolodny said. “It’s not a coincidence. That was the year Purdue launched a multifaceted campaign that misinformed the medical community about the risks.”²³³
- d. “Purdue had a speakers’ bureau, and it paid several thousand clinicians to attend medical conferences and deliver presentations about the merits of the drug. Doctors were offered all-expenses-paid trips to pain-management seminars in places like Boca Raton. Such spending was worth the investment: doctors who attended these seminars in 1996 wrote OxyContin prescriptions more than twice as often as those who didn’t. The company advertised in medical journals, sponsored Web sites about chronic pain, and distributed a dizzying variety of OxyContin swag: fishing hats, plush toys, luggage tags. Purdue also produced promotional videos featuring satisfied patients—like a construction worker who talked about how OxyContin had eased his chronic back pain, allowing him to return to work. The videos, which also included testimonials from pain specialists, were sent to tens of thousands of doctors. The marketing of OxyContin relied on an empirical circularity: the company

²³¹ Patrick R. Keefe, *The Family that Built an Empire of Pain*, THE NEW YORKER (Oct. 30, 2017), <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain>.

²³² *Id.*

²³³ *Id.*

convinced doctors of the drug's safety with literature that had been produced by doctors who were paid, or funded, by the company.”²³⁴

- e. Purdue encouraged sales representatives to increase sales of OxyContin through a lucrative bonus system, which resulted in a large number of visits to physicians with high rates of opioid prescriptions. In 2001, Purdue paid \$40 million in bonuses to its sales representatives.²³⁵
- f. Purdue claimed that the risk of addiction from OxyContin was extremely small and trained its sales representatives to carry the message that the risk of addiction was “less than one percent,” while knowing that there was no empirical support for that statement.
- g. By 2003, the Drug Enforcement Administration had found that Purdue’s “aggressive methods” had “very much exacerbated OxyContin’s widespread abuse.” Rogelio Guevara, a senior official at the D.E.A., concluded that Purdue had “deliberately minimized” the risks associated with the drug.²³⁶

540. “From 1996 to 2001, Purdue conducted more than 40 national pain-management and speaker training conferences at resorts in Florida, Arizona, and California. More than 5000 physicians, pharmacists, and nurses attended these all-expenses-paid symposia, where they were recruited and trained for Purdue’s national speaker bureau. It is well documented that this type of pharmaceutical company symposium influences physicians’ prescribing even though the physicians who attend such symposia believe that such enticements do not alter their prescribing patterns.”²³⁷

²³⁴ *Id.*

²³⁵ *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/>.

²³⁶ *The Family that Built an Empire of Pain*, <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain>

²³⁷ Art Van Zee, MD, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. Journal of Public Health 2 (Feb. 2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/>.

541. As noted above, Purdue utilized Front Groups to help disseminate and defend its false messages. Between January 2012 and March 2017, Purdue made the following contributions:

Academy of Integrative Pain Management	\$1,091,024.86
American Academy of Pain Management	\$725,584.95
ACS Cancer Action Network	\$168,500.00 ²³⁸
American Chronic Pain Association	\$312,470.00
American Geriatrics Society	\$11,785.00 ²³⁹
American Pain Foundation	\$25,000
American Pain Society	\$542,259.52
American Society of Pain Educators	\$30,000
American Society of Pain Management Nursing	\$242,535.00
The Center for Practical Bioethics	\$145,095.00
U.S. Pain Foundation	\$359,300.00
Washington Legal Foundation	\$500,000.00
TOTAL	\$4,153,554.33

²³⁸ Payments from Purdue to the American Cancer Society Cancer Action Network include payments to the American Cancer Society that could potentially have applied to the Cancer Action Network. Production from Purdue Pharma to the Senate Homeland Security and Governmental Affairs Committee (Nov. 13, 2017).

²³⁹ The AGS reported that Purdue also provided \$40,000 in “corporate roundtable dues” to its AGS Health in Aging Foundation, a 501(c)(3) organization affiliated with the group, between 2012 and 2015. Letter from Nancy E. Lundeberg, Chief Executive Office, American Geriatrics Society, to Sen. Claire McCaskill (Oct. 11, 2017).

2. Endo

542. Defendant Endo made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;
- d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;
- e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;
- f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- g. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Providing needed financial support to pro-opioid pain organizations – including over \$5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- i. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- l. Directly distributing and assisting in the dissemination of literature written by pro- opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and
- n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

3. Janssen

543. Defendant Janssen made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;

- d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;
- e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- i. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of

- abuse and addiction and the lack of validation for long-term efficacy;
- m. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and
 - n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

4. Depomed

544. Defendant Depomed has, since at least October 2011, made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive with respect to Lazanda and (with the acquisition from Janssen in January 2015) of Nucynta and Nucynta ER, including, but not limited to:

- a. Promoting the usage of Lazanda with patients not suffering from cancer;
- b. Endorsing, supporting, and pressuring its sales representative to target pain management physicians, particularly those who historically wrote large numbers of Lazanda-like drugs;
- c. Discouragement of sales representatives from targeting physicians treating cancer patients in contradiction to the FDA approved warning indicating that Lazanda is only indicated “for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain;”
- d. Training of sales representatives on how to deal with pushback from physicians;
- e. Promotion of Nucynta and Nucynta ER for all manner of pain management while downplaying the drug’s addictive nature;
- f. Promoting its drugs as a safer alternative than other opioids;
- g. Telling investors that Depomed is safe. August Moretti, Depomed’s Senior Vice President and Chief Financial Officer, stated that “[a]lthough not in the label, there’s a very low abuse profile and side effect rate.”

5. Cephalon

545. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;
- e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;
- h. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;
- i. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and

- j. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events.

6. Actavis

546. Defendant Actavis made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;
- c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

547. A Kadian prescriber guide deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. Kadian's prescriber guide is full of disclaimers that Actavis has not done any studies on the topic and that the guide is "only intended to assist you in forming your own conclusion." However, the guide includes the following statements: 1) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and 2) "KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state."

The guide is copyrighted by Actavis in 2007, before Actavis officially purchased Kadian from Alpharma.

7. Mallinckrodt

548. Defendant Mallinckrodt made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating and promoting publications that misrepresented and trivialized the risks of addiction;
- b. Creating and promoting publications that overstated the benefits of opioids for chronic pain; and
- c. Making deceptive statements about pseudoaddiction.

8. Insys

549. Defendant Insys made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Making deceptive statements concerning the appropriateness of the use of Subsys to treat neck and back and other chronic pain conditions without disclosing the lack of approval and lack of evidence for such uses;
- b. Implementing a kickback scheme wherein providers were incentivized to prescribe Subsys in exchange for payment as speakers in fake speakers' programs; and
- c. Obtaining authorization for approval of payor reimbursement for Subsys through a deceptive prior authorization program that falsified patient medical histories, falsely claimed that patients had cancer, and provided misleading information to insurers and payors regarding patients' diagnoses and medical conditions.

550. Insys's opioid, Subsys, was approved by the FDA in 2012 for the "management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain." Under FDA rules,

Insys could only market Subsys for this use. Subsys consists of the highly addictive narcotic, fentanyl, administered via a sublingual (under the tongue) spray, which provides rapid-onset pain relief. It is in the class of drugs described as Transmucosal Immediate-Release Fentanyl (“TIRF”).

551. To reduce the risk of abuse, misuse, and diversion, the FDA instituted a REMS (Risk Evaluation and Medication Strategy) for Subsys and other TIRF products, such as Cephalon’s Actiq and Fentora. The purpose of the REMS was to educate “prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose” for this type of drug and to “ensure safe use and access to these drugs for patients who need them.”²⁴⁰ Prescribers must enroll in the TIRF REMS before writing a prescription for Subsys.

552. Since its launch, Subsys has been an extremely expensive medication, and has increased its prices every year. Depending on a patient’s dosage and frequency of use, a month’s supply of Subsys could cost in the thousands of dollars.

553. Due to its high cost, in most instances prescribers must submit Subsys prescriptions to insurance companies or health benefit payors for prior authorization to determine whether they will pay for the drug prior to the patient attempting to fill the prescription. According to the U.S. Senate Homeland Security and Governmental Affairs Committee Minority Staff Report (“Staff Report”), the prior authorization process includes “confirmation that the patient had an active cancer diagnosis, was being treated by an opioid (and, thus, was opioid tolerant), and was being prescribed Subsys to treat breakthrough pain that the other opioid could not eliminate. If any one of these factors was not present, the prior authorization would be denied . . .”²⁴¹

²⁴⁰ Press Release, FDA, *FDA Approves Shared System REMS for TIRF Products*, (Dec. 29, 2011).

²⁴¹ U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members’ Office, Staff Report, *Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization* (Sept. 6, 2017), <https://www.hsdl.org/?view&did=803959>.

554. These prior authorization requirements proved to be daunting. Subsys received reimbursement approval in only approximately 30% of submitted claims. In order to increase approvals, Insys created a prior authorization unit, called the Insys Reimbursement Center (“IRC”), to obtain approval for Subsys reimbursements. This unit employed a number of fraudulent and misleading tactics to secure reimbursements, including falsifying medical histories of patients, falsely claiming that patients had cancer, and providing misleading information to insurers and payors regarding patients’ diagnoses and medical conditions.

555. Subsys has proved to be extremely profitable for Insys. Insys made approximately \$330 million in net revenue from Subsys last year. Between 2013 and 2016, the value of Insys stock rose 296%.

556. Since its launch in 2012, Insys aggressively worked to grow its profits through fraudulent, illegal, and misleading tactics, including its reimbursement-related fraud. Through its sales representatives and other marketing efforts, Insys deceptively promoted Subsys as safe and appropriate for uses such as neck and back pain, without disclosing the lack of approval or evidence for such uses, and misrepresented the appropriateness of Subsys for treatment of those conditions. It implemented a kickback scheme wherein it paid prescribers for fake speaker programs in exchange for prescribing Subsys. All of these fraudulent and misleading schemes had the effect of pushing Insys’s dangerous opioid onto patients who did not need it.

557. Insys incentivized its sales force to engage in illegal and fraudulent conduct. Many of the Insys sales representatives were new to the pharmaceutical industry and their base salaries were low compared to industry standard. The compensation structure was heavily weighted toward commissions and rewarded representatives more for selling higher (and more expensive) doses of

Subsys, a “highly unusual” practice because most companies consider dosing a patient-specific decision that should be made by a doctor.²⁴²

558. The Insys “speakers program” was perhaps its most widespread and damaging scheme. A former Insys salesman, Ray Furchak, alleged in a qui tam action that the sole purpose of the speakers program was “in the words of his then supervisor Alec Burlakoff, ‘to get money in the doctor’s pocket.’” Furchak went on to explain that “[t]he catch . . . was that doctors who increased the level of Subsys prescriptions, and at higher dosages (such as 400 or 800 micrograms instead of 200 micrograms), would receive the invitations to the program—and the checks.”²⁴³ It was a pay-to-prescribe program.

559. Insys’s sham speaker program and other fraudulent and illegal tactics have been outlined in great detail in indictments and guilty pleas of Insys executives, employees, and prescribers across the country, as well as in a number of lawsuits against the company itself.

560. In May of 2015, two Alabama pain specialists were arrested and charged with illegal prescription drug distribution, among other charges. The doctors were the top prescribers of Subsys, though neither were oncologists. According to prosecutors, the doctors received illegal kickbacks from Insys for prescribing Subsys. Both doctors had prescribed Subsys to treat neck, back, and joint pain. In February of 2016, a former Insys sales manager pled guilty to conspiracy to commit health care fraud, including engaging in a kickback scheme in order to induce one of these doctors to prescribe Subsys. The plea agreement states that nearly all of the Subsys prescriptions written by the doctor were off-label to non-cancer patients. In May of 2017, one of the doctors was sentenced to 20 years in prison.

²⁴² *Id.*

²⁴³ Roddy Boyd, *Insys Therapeutics and the New “Killing It”*, Southern Investigative Reporting Foundation, THE INVESTIGATOR (April 24, 2015), <http://sirf-online.org/2015/04/24/the-new-killing-it/>.

561. In June of 2015, a nurse practitioner in Connecticut, described as the state's highest Medicare prescriber of narcotics, pled guilty to receiving \$83,000 in kickbacks from Insys for prescribing Subsys. Most of her patients were prescribed the drug for chronic pain. Insys paid the nurse as a speaker for more than 70 dinner programs at approximately \$1,000 per event; however, she did not give any presentations. In her guilty plea, the nurse admitted receiving the speaker fees in exchange for writing prescriptions for Subsys.

562. In August of 2015, Insys settled a complaint brought by the Oregon Attorney General. In its complaint, the Oregon Department of Justice cited Insys for, among other things, misrepresenting to doctors that Subsys could be used to treat migraine, neck pain, back pain, and other uses for which Subsys is neither safe nor effective, and using speaking fees as kickbacks to incentivize doctors to prescribe Subsys.

563. In August of 2016, the State of Illinois sued Insys for similar deceptive and illegal practices. The Complaint alleged that Insys marketed Subsys to high-volume prescribers of opioid drugs instead of to oncologists whose patients experienced the breakthrough cancer pain for which the drug is indicated. The Illinois Complaint also details how Insys used its speaker program to pay high volume prescribers to prescribe Subsys. The speaker events took place at upscale restaurants in the Chicago area, and Illinois speakers received an "honorarium" ranging from \$700 to \$5,100, and they were allowed to order as much food and alcohol as they wanted. At most of the events, the "speaker" being paid by Insys did not speak, and, on many occasions, the only attendees at the events were the speaker and an Insys sales representative.

564. In December of 2016, six Insys executives and managers were indicted and then, in October 2017, Insys's founder and owner was arrested and charged with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud

insurance companies. A U.S. Department of Justice press release explained that, among other things: “Insys executives improperly influenced health care providers to prescribe a powerful opioid for patients who did not need it, and without complying with FDA requirements, thus putting patients at risk and contributing to the current opioid crisis.”²⁴⁴ The DEA Special Agent in Charge further explained that: “Pharmaceutical companies whose products include controlled medications that can lead to addiction and overdose have a special obligation to operate in a trustworthy, transparent manner, because their customers’ health and safety and, indeed, very lives depend on it.”²⁴⁵

VI. DEFENDANTS THROUGHOUT THE SUPPLY CHAIN DELIBERATELY DISREGARDED THEIR DUTIES TO MAINTAIN EFFECTIVE CONTROLS AND TO IDENTIFY, REPORT, AND TAKE STEPS TO HALT SUSPICIOUS ORDERS

565. The Marketing Defendants created a vastly and dangerously larger market for opioids. All of the Defendants compounded this harm by facilitating the supply of far more opioids that could have been justified to serve that market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious breached both their statutory and common law duties.

566. Marketing Defendants’ scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. Marketing Defendants’ deceptive marketing caused prescribing not only of their opioids, but also of opioids as a class, to skyrocket. According to the CDC opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent

²⁴⁴ Press Release, DOJ, U.S. Attorney’s Office, Dist. of Mass., *Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering* (Oct. 26, 2017), available at <https://www.justice.gov/usao-ma/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering>.

²⁴⁵ *Id.*

(“MME”) per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids.

567. In a 2016 report, the CDC explained that “[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses.”²⁴⁶ Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”²⁴⁷

A. All Defendants Have, and Breached, Duties to Guard Against, and Report, Unlawful Diversion and to Report and Prevent Suspicious Orders

568. Multiple sources impose duties on Defendants with respect to the supply of opioids, including the common law duty to exercise reasonable care.

569. Each Defendant was required to register with the DEA, pursuant to the CSA. *See* 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100. Each Defendant is a “registrant” of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. Each Defendant has an affirmative duty under federal law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that “requirements” of Schedule II drugs, including opioids, must maintain “effective

²⁴⁶ CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd, Rose A., et al., “Increases in drug and opioid overdose deaths—United States, 2000–2014.” American Journal of Transplantation 16.4 (2016): 1323-1327.

²⁴⁷ *Id.*

control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.” 21 U.S.C. §§ 823(b)(1).

570. Each Defendant was also required to register with state boards of pharmacy, or the equivalent, and certify (with the states) compliance with state and federal law. The Defendants also had legal duties under state common law, statutes and regulations to maintain adequate records, and prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids. Defendants violated state laws prohibiting false advertising or other false statements relating to drugs. This includes the common law of fraud, statutes designed to generally prohibit unfair and deceptive acts in commerce, as well as statutes specifically prohibiting deceptive practice relating to drugs.

571. Under federal law, too, distributors, opioid manufacturers are required to “design and operate a system to disclose . . . suspicious orders of controlled substances” and to maintain “effective controls against diversion.” 21 C.F.R. § 1301.74; 21 USCA § 823(a)(1). Federal requirements impose a non-delegable duty upon registrants to design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. § 1301.74(b). “Suspicious orders” include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. *See* 21 C.F.R. § 1301.74(b). These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a normal pattern to develop over time before determining whether a particular order

is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry.

572. In addition to reporting all suspicious orders, the Distributor Defendants must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the recipient can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F. 3d 206 (D.C. 2017). Regardless, all flagged orders must be reported. *Id.*

573. These prescription drugs are regulated for the purpose of providing a “closed” system intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.²⁴⁸

574. “Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant’s role and

²⁴⁸ See 1970 U.S.C.C.A.N. 4566, 4571-72.

responsibilities.”²⁴⁹

575. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction, with costs and damages necessarily inflicted on and incurred by Plaintiffs and others.

576. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality, along with the costs imposed upon Plaintiffs and others associated with the treatment of these conditions and related health consequences caused by opioid abuse.

577. Finding it impossible to legally achieve their ever-increasing sales ambitions, Defendants engaged in the common purpose of increasing the supply of opioids and fraudulently increasing the quotas that governed the manufacture and distribution of their prescription opioids.

578. Wholesale distributors such as the Distributor Defendants had close financial relationships with both Marketing Defendants and customers, for whom they provide a broad range of value-added services that render them uniquely positioned to obtain information and control against diversion. These services often otherwise would not be provided by manufacturers to their dispensing customers and would be difficult and costly for the dispenser to reproduce. For

²⁴⁹ Brief for Healthcare Distribution Mgmt. Ass’n of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf’t Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 (hereinafter “Brief for HDMA and NACDS”). The Healthcare Distribution Mgmt. Ass’n (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation’s primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation and Cardinal Health, Inc. *See generally* HDA, *About*, <https://www.healthcaredistribution.org/about> (last accessed Aug. 1, 2018). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. *See generally* NACDS, *Mission*, <https://www.nacds.org/%20about/mission/> (last accessed Aug. 1, 2018).

example, “[w]holesalers have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers’ stock.” *Fed. Trade Comm’n v. Cardinal Health, Inc.*, 12 Supp. 2d 34, 41 (D.D.C. 1998). Through their generic source programs, wholesalers are also able “to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers.” Wholesalers typically also offer marketing programs, patient services, and other software to assist their dispensing customers.

579. Distributor Defendants had financial incentives from the Marketing Defendants to distribute higher volumes and thus to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.

580. The Marketing Defendants engaged in the practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids as a way to help them boost sales and better target their marketing efforts. The Washington Post has described the practice as industry-wide, and the Healthcare Distribution Alliance (“HDA”) includes a “Contracts and Chargebacks Working Group,” suggesting a standard practice. Further, in a recent settlement with the DEA, Mallinckrodt acknowledged that “[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors).” The transaction information contains data relating to the direct customer sales of

controlled substances to “downstream registrants”, meaning pharmacies or other dispensaries, such as hospitals. Marketing Defendants buy data from pharmacies as well. This exchange of information, upon information and belief, would have opened channels providing for the exchange of information revealing suspicious orders as well.

581. A dramatic example of the use of prescription information provided by IMS Health was described in Congressional testimony:

Mr. Greenwood: Well, why do you want that [IMS Health] information then?

Mr. Friedman: Well, we use that information to understand what is happening in terms of the development of use of our product in any area.

Mr. Greenwood. And so the use of it--and I assume that part of it--a large part of it you want is to see how successful your marketing techniques are so that you can expend money in a particular region or among a particular group of physicians-- you look to see if your marketing practices are increased in sales. And, if not, you go back to the drawing board with your marketers and say, how come we spent “X” number of dollars, according to these physicians, and sales haven't responded. You do that kind of thing. Right?

Mr. Friedman: Sure.²⁵⁰

582. The contractual relationships among the Defendants also include vault security programs. Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. The Defendants negotiated agreements whereby the Marketing Defendants installed security vaults for the Distributor Defendants in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by

²⁵⁰ *Oxycontin: Its Use and Abuse: Hearing Before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce House of Representatives*, 107th Cong. 54 (2001) (statements of James C. Greenwood, Member, Committee on Energy and Commerce and Michael Friedman, Executive Vice President and COO of Purdue Pharma, L.P.), available at <https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/html/CHRG-107hhrg75754.htm>.

the Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

1. Defendants' Use of Trade and Other Organizations

583. In addition, Defendants worked together to achieve their common purpose through trade or other organizations, such as the Pain Care Forum (“PCF”) and the HDA.

a. Pain Care Forum

584. PCF has been described as a coalition of drug makers, trade groups, and dozens of non-profit organizations supported by industry funding, including the Front Groups described in this Complaint. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

585. The Center for Public Integrity and The Associated Press obtained “internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse.”²⁵¹ Specifically, PCF members spent over \$740 million lobbying in the nation’s capital and in all 50 statehouses on an array of issues, including opioid-related measures.²⁵²

586. The Defendants who stood to profit from expanded prescription opioid use are members of and/or participants in the PCF.²⁵³ In 2012, membership and participating

²⁵¹ Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic*, The Center for Public Integrity (Sept. 19, 2017, 12:01 a.m.), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic>. (emphasis added).

²⁵² *Id.*

²⁵³ *PAIN CARE FORUM 2012 Meetings Schedule*, (last updated Dec. 2011), <https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf>.

organizations included Endo, Purdue, Actavis and Cephalon. Each of the Marketing Defendants worked together through the PCF. But the Marketing Defendants were not alone. The Distributor Defendants actively participated, and continue to participate, in the PCF through, at a minimum, their trade organization, the HDA.²⁵⁴ The Distributor Defendants participated directly in the PCF as well.

b. HDA

587. Additionally, the HDA led to the formation of interpersonal relationships and an organization among the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Marketing Defendants, including Actavis, Endo, Purdue, Mallinckrodt and Cephalon, were members of the HDA.²⁵⁵ Additionally, the HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Marketing Defendants by advocating for the many benefits of members, including “strengthening . . . alliances.”²⁵⁶

588. Beyond strengthening alliances, the benefits of HDA membership included the ability to, among other things, “network one on one with manufacturer executives at HDA’s members-only Business and Leadership Conference,” “networking with HDA wholesale distributor members,” “opportunities to host and sponsor HDA Board of Directors events,” “participate on HDA committees, task forces and working groups with peers and trading partners,”

²⁵⁴ *Id.* The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc. and the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation. *Executive Committee*, Healthcare Distribution Alliance (last accessed on Aug. 1, 2018), <https://www.healthcaredistribution.org/about/executive-committee%20>.

²⁵⁵ *Manufacturer Membership*, Healthcare Distribution Alliance, <https://www.healthcaredistribution.org/about/membership/manufacturer> (last accessed Aug. 1, 2018).

²⁵⁶ *Id.*

and “make connections.”²⁵⁷ The HDA and the Supply Chain Defendants used membership in the HDA as an opportunity to create interpersonal and ongoing organizational relationships and “alliances” between the Marketing and Supply Chain Defendants.

589. The application for manufacturer membership in the HDA further indicates the level of connection among the Defendants and the level of insight that they had into each other’s businesses.²⁵⁸ For example, the manufacturer membership application must be signed by a “senior company executive,” and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company.

590. The HDA application also requests that the manufacturer identify its current distribution information, including the facility name and contact information. Manufacturer members were also asked to identify their “most recent year end net sales” through wholesale distributors, including the Distributor Defendants AmerisourceBergen, Anda, Cardinal, and Henry Schein and their subsidiaries.

591. The closed meetings of the HDA’s councils, committees, task forces and working groups provided the Marketing and Distributor Defendants with the opportunity to work closely together, confidentially, to develop and further the common purpose and interests of the enterprise.

592. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Marketing Defendants as an opportunity to “bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing

²⁵⁷ *Id.*

²⁵⁸ *Id.*

industry issues.”²⁵⁹ The conferences also gave the Marketing and Distributor Defendants “unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry.”²⁶⁰ The HDA and its conferences were significant opportunities for the Marketing and Distributor Defendants to interact at a high-level of leadership. The Marketing Defendants embraced this opportunity by attending and sponsoring these events.²⁶¹

593. After becoming members of the HDA, Defendants were eligible to participate on councils, committees, task forces and working groups, including:

- a. Industry Relations Council: “This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues.”
- b. Business Technology Committee: “This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee’s major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce.” Participation in this committee includes distributor and manufacturer members.
- c. Logistics Operation Committee: “This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement.” Participation in this committee includes distributor and manufacturer members.
- d. Manufacturer Government Affairs Advisory Committee: “This committee provides a forum for briefing HDA’s manufacturer members on federal and state legislative and regulatory activity

²⁵⁹ *Business and Leadership Conference – Information for Manufacturers*, Healthcare Distribution Alliance, <https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers> (last accessed Aug. 1, 2018, and no longer available).

²⁶⁰ *Id.*

²⁶¹ *2015 Distribution Management Conference and Expo*, Healthcare Distribution Alliance, <https://www.healthcaredistribution.org/events/2015-distribution-management-conference>. (last accessed Aug. 1, 2018).

affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement.” Participation in this committee includes manufacturer members.

- e. Contracts and Chargebacks Working Group: “This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals.” Participation in this group includes manufacturer and distributor members.

594. The Distributor Defendants and Marketing Defendants also participated, through the HDA, in Webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.²⁶² For example, on April 27, 2011, the HDA offered a Webinar to “accurately and effectively exchange business transactions between distributors and manufacturers...” The Marketing Defendants used this information to gather high-level data regarding overall distribution and to direct the Distributor Defendants on how to most effectively sell prescription opioids.

595. Taken together, the interaction and length of the relationships between and among the Marketing and Distributor Defendants reflect a deep level of interaction and cooperation between two groups in a tightly knit industry. The Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

596. The HDA and the Pain Care Forum are but two examples of the overlapping relationships and concerted joint efforts to accomplish common goals and demonstrates that the

²⁶² *Webinars*, Healthcare Distribution Alliance, (last accessed on Sept. 14, 2017), <https://www.healthcaredistribution.org/resources/webinar-leveraging-edi>.

leaders of each of the Defendants were in communication and cooperation.

597. Publications and guidelines issued by the HDA confirm that the Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of 2008, the HDA published the *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances* (the “Industry Compliance Guidelines”) regarding diversion. As the HDA explained in an amicus brief, the Industry Compliance Guidelines were the result of “[a] committee of HDMA members contribut[ing] to the development of this publication” beginning in late 2007.

598. This statement by the HDA and the Industry Compliance Guidelines support the allegation that Defendants utilized the HDA to form agreements about their approach to their duties under the CSA. As John M. Gray, President/CEO of the HDA stated to the Energy and Commerce Subcommittee on Health in April 2014, it is “difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications.” Here, it is apparent that all of the Defendants found the same balance – an overwhelming pattern and practice of failing to identify, report or halt suspicious orders, and failure to prevent diversion.

599. The Defendants’ scheme had a decision-making structure driven by the Marketing Defendants and corroborated by the Distributor Defendants. The Marketing Defendants worked together to control the state and federal government’s response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion and identify suspicious orders and report them to the DEA.

600. The Defendants worked together to control the flow of information and to influence state and federal governments to pass legislation that supported the use of opioids and limited the

authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. The Marketing and Distributor Defendants did this through their participation in the PCF and HDA.

601. The Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas, and Procurement Quotas allowed by the DEA remained artificially high. In so doing, they ensured that suspicious orders were not reported to the DEA, and, further, in so doing, they ensured that the DEA had no basis for either refusing to increase production quotas or decreasing production quotas due to diversion.

602. The Defendants also had reciprocal obligations under the CSA to report suspicious orders of other parties if they became aware of them. Defendants were thus collectively responsible for each other's compliance with reporting obligations.

603. Defendants thus knew that their own conduct could be reported by other distributors or manufacturers and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency in their dealings with DEA.

604. The desired consistency was achieved. As described below, none of the Defendants reported suspicious orders and the flow of opioids continued unimpeded.

2. Defendants Were Aware of and Have Acknowledged Their Obligations to Prevent Diversion and to Report and Take Steps to Halt Suspicious Orders

605. The reason for the reporting rules is to create a "closed" system intended to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. Both because distributors handle such large volumes of controlled substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled

substances from legitimate channels into the illicit market, distributors' obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.²⁶³

606. Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

3. Defendants Kept Careful Track of Prescribing Data and Knew About Suspicious Orders and Prescribers

607. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's Confidential Automation of Reports and Consolidated Orders System (ARCOS) database. The data necessary to identify with specificity the transactions that were suspicious is in possession of the Distributor and Marketing Defendants but has not been disclosed to the public.

608. Publicly available information confirms that Distributor and Marketing Defendants funneled far more opioids into communities across the United States than could have been expected to serve legitimate medical use and ignored other red flags of suspicious orders. This information, along with the information known only to Distributor and Marketing Defendants, would have alerted them to potentially suspicious orders of opioids.

609. This information includes the following facts:

- a. distributors and manufacturers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;

²⁶³ See Rannazzisi Decl. ¶ 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

- b. manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;
- c. manufacturers and distributors regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion;
- d. Distributor Defendants together account for approximately 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; and
- e. Marketing Defendants purchased chargeback data (in return for discounts to Distributor Defendants) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.

610. The conclusion that Defendants were on notice of the problems of abuse and diversion follows inescapably from the fact that they flooded communities with opioids in quantities that they knew or should have known exceeded any legitimate market for opioids—even the wider market for chronic pain.

611. At all relevant times, the Defendants were in possession of national, regional, state, and local prescriber-and patient-level data that allowed them to track prescribing patterns over time. They obtained this information from data companies, including but not limited to: IMS Health, QuintilesIMS, IQVIA, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or PRA Health Science, and all of their predecessors or successors in interest (the “Data Vendors”).

612. The Distributor Defendants developed “know your customer” questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help the Defendants identify suspicious orders or customers who were likely to divert

prescription opioids.²⁶⁴ The “know your customer” questionnaires informed the Defendants of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy purchased opioids from other distributors, and the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, and others. These questionnaires put the recipients on notice of suspicious orders.

613. Defendants purchased nationwide, regional, state, and local prescriber- and patient-level data from the Data Vendors that allowed them to track prescribing trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills, etc. The Data Vendors’ information purchased by the Defendants allowed them to view, analyze, compute, and track their competitors’ sales, and to compare and analyze market share information.²⁶⁵

614. IMS Health, for example, provided Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.²⁶⁶

615. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by Cardinal (ArcLight), provided the Defendants with charts analyzing the

²⁶⁴ *Suggested Questions a Distributor should ask prior to shipping controlled substances*, DEA, https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levin1_ques.pdf; Richard Widup, Jr., Kathleen H. Dooley, Esq. *Pharmaceutical Product Diversion: Beyond the PDMA*, Purdue Pharma and McGuireWoods LLC, https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf.

²⁶⁵ A Verispan representative testified that the Supply Chain Defendants use the prescribing information to “drive market share.” *Sorrell v. IMS Health Inc.*, 2011 WL 661712, *9-10 (Feb. 22, 2011).

²⁶⁶ Paul Kallukaran & Jerry Kagan, *Data Mining at IMS HEALTH: How we Turned a Mountain of Data into a Few Information-rich Molehills*, <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.198.349&rep=rep1&type=pdf>, Figure 2 at p. 3 (last accessed Aug. 1, 2018).

weekly prescribing patterns of multiple physicians, organized by territory, regarding competing drugs and analyzed the market share of those drugs.²⁶⁷

616. This information allowed the Defendants to track and identify instances of overprescribing. In fact, one of the Data Vendors' experts testified that the Data Vendors' information could be used to track, identify, report and halt suspicious orders of controlled substances.²⁶⁸ Defendants were, therefore, collectively aware of the suspicious orders that flowed from their facilities.

617. Defendants refused to identify, investigate, and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. As described in detail below, Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012²⁶⁹ and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders, all for failure to report suspicious orders.²⁷⁰

618. Sales representatives were also aware that the prescription opioids they were promoting were being diverted, often with lethal consequences. As a sales representative wrote on a public forum:

Actions have consequences - so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got "sold" on

²⁶⁷ *Sorrell v. IMS Health Inc.*, 2011 WL 705207, at *467-471 (Feb. 22, 2011).

²⁶⁸ In *Sorrell*, expert Eugene "Mick" Kolassa testified, on behalf of the Data Vender, that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product." *Id.*; see also Joint Appendix in *Sorrell v. IMS Health*, 2011 WL 687134, at *204 (Feb. 22, 2011).

²⁶⁹ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

²⁷⁰ *Id.*

the 80mg) and their teen son/daughter/child’s teen friend finds the pill bottle and takes out a few 80’s... next they’re at a pill party with other teens and some kid picks out a green pill from the bowl... they go to sleep and don’t wake up (because they don’t understand respiratory depression). Stupid decision for a teen to make...yes... but do they really deserve to die?

619. Moreover, Defendants’ sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions, the DEA’s diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors. But Purdue’s sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time, Wilson was Purdue’s top-ranked sales representative.²⁷¹ In response to news stories about this clinic, Purdue issued a statement, declaring that “if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not.”²⁷²

2. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative, “it was packed with a line out the door, with people who looked like gang members,” and that she felt “very certain that this an organized drug ring[.]”²⁷³ She wrote, “This is clearly diversion. Shouldn’t the DEA be contacted about this?” But her supervisor at Purdue

²⁷¹ *Pain Killer*, at 298-300.

²⁷² *Id.*

²⁷³ Harriet Ryan et al., *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drug maker knew*, LOS ANGELES TIMES (July 10, 2016), <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

responded that while they were “considering all angles,” it was “really up to [the wholesaler] to make the report.”²⁷⁴ This pill mill was not only distributing opioids locally - over a million pills were transported to the City of Everett, Washington, a city of around 100,000 people. Couriers drove up I-5 through California and Oregon, or flew from Los Angeles to Seattle. The Everett-based dealer who received the pills from southern California wore a diamond necklace in the shape of the West Coast states with a trail of green gemstones—the color of 80-milligram OxyContin—connecting Los Angeles and Washington state. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.

620. At Purdue, the Purdue Individual Defendants were well aware of the importance of prolific prescribers, which they and their staff referred to internally, at times, as “core,” “super core,” “high value” and “high potential” prescribers. In fact, it was an explicit, and significant, sales strategy to pay particular attention to actual and potential prolific prescribers, which the Purdue Individual Defendants understood to account for approximately 10% of overall revenues.

621. The Purdue Individual Defendants were also aware that Purdue regularly received “Reports of Concern” about abuse and diversion of opioids, as well as reports of other adverse events, and also calls to Purdue’s compliance “hotline.” In July 2007, staff told the Sackler Defendants that more than 5,000 cases of adverse events had been reported to Purdue in just the first three months of 2007. Staff also told the Sackler Defendants that Purdue received 572 Reports of Concern about abuse and diversion of Purdue opioids during Q2 2007 — including several reports in Massachusetts. Staff reported to the Sackler Defendants that they completed only 21 field inquiries in response. Staff also told the Sackler Defendants that they received more than 100 calls to Purdue’s compliance hotline during the quarter, which was a “significant increase,” but

²⁷⁴*Id.*

Purdue did not report any of the hotline calls or Reports of Concern to the FDA, DEA, Department of Justice, or state authorities.

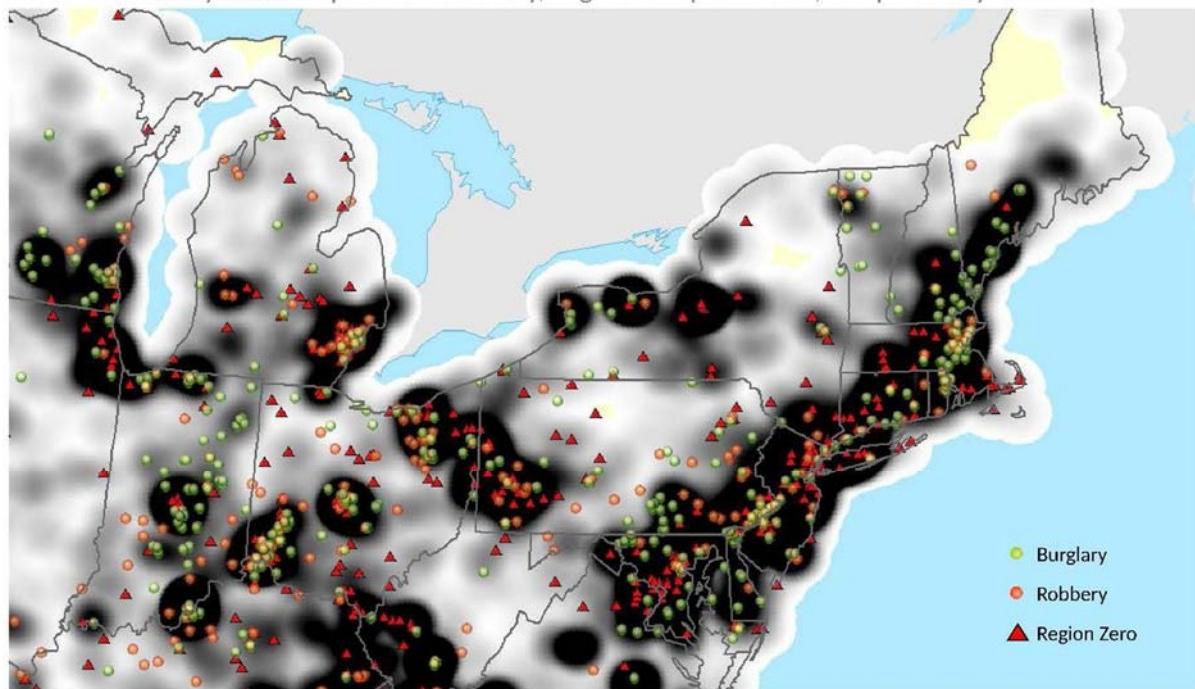
622. The Purdue Defendants' self-interested failure to report abuse and diversion would continue, quarter after quarter, even though the 2007 Judgment required Purdue to report "potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities." Instead of reporting dangerous prescribers, or even directing sales reps to stop visiting them, the Sacklers chose to keep pushing opioids to whoever prescribed the most.¹⁰⁰

623. Purdue also tracked prescribers from whom there was a substantial possibility of opioids having been diverted, or, at a minimum, grossly over-prescribed. It described these prescribers as, collectively, "Region Zero," and even generated a map, given to members of the Board, correlating these prescribers with poison control calls and pharmacy thefts.

We are examining the spatial relationship between different aspects of the abuse environment

ILLUSTRATIVE

Poison Control oxycodone exposure call density, Region Zero prescribers, and pharmacy theft



SOURCE: AAPCC, PPLP, RxPatrol

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Map presented to the Purdue Board in 2011

Once prescribers were categorized as part of “Region Zero,” Purdue would eventually stop promoting to them, but it would *not* stop selling to them, and it would *not* report them to authorities. This would have been costly. Staff told Defendant John Stewart and the Board that the company was receiving a steadily rising volume of hotline calls and other compliance matters, in this time frame, reaching an all-time high during October, November, and December 2010

624. Purdue made a calculated economic decision *not* to report suspicious prescribers and orders. Indeed, an internal Purdue study showed that the financial penalties imposed on drug companies for illegal marketing were “relatively small” when “compared to the perpetrating companies’ profits.” When the U.S. Centers for Disease Control issued a national warning against the highest and most dangerous doses of opioids, Purdue studied prescription data to calculate how

much profit it would lose if doctors followed the CDC's advice, and it elected not to.

625. Defendants' obligation to report suspicious prescribing ran head on into their marketing strategy. Defendants did identify doctors who were their most prolific prescribers. However, this was done not to report them, but to market to them. It would make little sense to focus on marketing to doctors who may be engaged in improper prescribing only to report them to law enforcement.

626. Defendants purchased data from IMS Health (now IQVIA) or other proprietary sources to identify doctors to target for marketing and to monitor their own and competitors' sales. Marketing visits were focused on increasing, sustaining, or converting the prescriptions of the biggest prescribers, particularly through aggressive, high frequency detailing visits.

627. This focus on marketing to the highest prescribers demonstrates that manufacturers were keenly aware of the doctors who were writing large quantities of opioids. But instead of investigating or reporting those doctors, Defendants were singularly focused on maintaining, capturing, or increasing their sales.

628. Whenever examples of opioid diversion and abuse have drawn media attention, Purdue and other Marketing Defendants have consistently blamed "bad actors." For example, in 2001, during a Congressional hearing, Purdue's attorney Howard Udell answered pointed questions about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell asserted that Purdue was "fooled" by the doctor: "The picture that is painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon this community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He

fooled the DEA. He fooled local law enforcement. He fooled us.”²⁷⁵

629. But given the closeness with which they monitored prescribing patterns through IMS Health data, the Defendants either knew or chose not to know of the obvious drug diversions. In fact, a local pharmacist had noticed the volume of prescriptions coming from Paolino’s clinic and alerted authorities. Purdue had the prescribing data from the clinic and alerted no one. Indeed, a Purdue executive referred to Purdue’s tracking system and database as a “gold mine” and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

630. As discussed below, Endo knew that Opana ER was being widely abused. Yet, the New York Attorney General revealed, based on information obtained in an investigation into Endo, that Endo sales representatives were not aware that they had a duty to report suspicious activity and were not trained on the company’s policies or duties to report suspicious activity, and Endo paid bonuses to sales representatives for detailing prescribers who were subsequently arrested for illegal prescribing.

631. Sales representatives making in-person visits to such clinics were likewise not fooled. But as pill mills were lucrative for the manufacturers and individual sales representatives alike, Marketing Defendants and their employees turned a collective blind eye, allowing certain clinics to dispense staggering quantities of potent opioids and feigning surprise when the most egregious examples eventually made the nightly news.

4. Defendants Failed to Report Suspicious Orders or Otherwise Act to Prevent Diversion

632. As discussed above, Defendants failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids flowing into communities across America. Despite the notice described above, Defendants continued to pump massive quantities of opioids

²⁷⁵ *Pain Killer*, at 179.

into communities in disregard of their legal duties to control the supply, prevent diversion, and report and take steps to halt suspicious orders.

633. Governmental agencies and regulators have confirmed (and in some cases Defendants have admitted) that Defendants did not meet their obligations and have uncovered especially blatant wrongdoing.

634. For example, in 2017, the Department of Justice fined Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements. The government alleged that “Mallinckrodt failed to design and implement an effective system to detect and report ‘suspicious orders’ for controlled substances - orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders.”

635. On December 23, 2016, Cardinal agreed to pay the United States \$44 million to resolve allegations that it violated the CSA in Maryland, Florida, and New York by failing to report suspicious orders of controlled substances, including oxycodone, to the DEA. In the settlement agreement, Cardinal admitted, accepted, and acknowledged that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to:

- a. “timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b);”
- b. “maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. §1301.74, including the failure to make records and reports required by the CSA or DEA’s regulations for which a penalty may be imposed under 21 U.S.C. §842(a)(5); and

- c. "execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA 'Form 222' order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. §828 and 21 C.F.R. Part 1305."

636. In 2012, the State of West Virginia sued AmerisourceBergen and Cardinal, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection and antitrust laws, and the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with Cardinal, shipped 423 million pain pills to West Virginia between 2007 and 2012. AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 million oxycodone pills during that time period. These quantities demonstrate that the Defendants failed to control the supply chain or to report and take steps to halt suspicious orders. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit for \$16 million to the state; Cardinal settled for \$20 million.

637. Henry Schein, too, is a repeat offender. Since the company's inception, it has been subjected to repeated disciplinary actions across the United States for its sale and/or distribution of dangerous drugs to persons or facilities not licensed or otherwise authorized to possess such drugs.

638. In 2014, Henry Schein Animal Health was investigated by the State of Ohio Board of Pharmacy due to its sale/distribution of wholesale dangerous drugs to an entity not holding a valid Ohio license. It reached a settlement with the Ohio Board of Pharmacy related to this investigation in 2015.

639. Records from a disciplinary proceeding against a Wisconsin-licensed medical practitioner reveal that from May 2005 through September 2006, Henry Schein continued to deliver opioids to the provider, despite the fact that his license had been suspended for inappropriate prescribing of opioids.

640. Thus, Defendants have admitted to disregarding their duties. They have admitted that they pumped massive quantities of opioids into communities around the country despite their obligations to control the supply, prevent diversions, and report and take steps to halt suspicious orders.

5. Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement

641. When a manufacturer or distributor does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action - or may not know to take action at all.

642. After being caught failing to comply with particular obligations at particular facilities, Distributor Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens.

643. More generally, the Distributor Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs. For example, Defendant Cardinal claims that: “We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing ‘the right thing’ serves everyone.” Defendant Cardinal likewise claims to “lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse.” Along the same lines, it claims to “maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription-controlled medications that do not meet [its] strict criteria.” Defendant

Cardinal also promotes funding it provides for “Generation Rx,” which funds grants related to prescription drug misuse. A Cardinal executive recently claimed that Cardinal uses “advanced analytics” to monitor its supply chain; Cardinal assured the public it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”

644. Along the same lines, Defendant AmerisourceBergen has taken the public position that it is “work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse of controlled substances.” A company spokeswoman also provided assurance that: “At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients.”

645. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Supply Chain Defendants, through their trade associations, HDMA and NACDS, filed an amicus brief in *Masters Pharmaceuticals*, which made the following statements:²⁷⁶

- a. “HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”
- b. “Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that is available to them in the ordering process.”

646. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the

²⁷⁶ Brief for HDMA and NACDS, 2016 WL 1321983, at *3-4, *25.

Supply Chain Defendants not only acknowledged that they understood their obligations under the law, but they further asserted that their conduct was in compliance with those obligations.

647. Defendant Mallinckrodt similarly claims to be “committed . . . to fighting opioid misuse and abuse,” and further asserts that: “In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances . . .”

648. Other Marketing Defendants also misrepresented their compliance with their legal duties and their cooperation with law enforcement. Purdue serves as a hallmark example of such wrongful conduct. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its “constructive role in the fight against opioid abuse,” including its commitment to ADF opioids and its “strong record of coordination with law enforcement.²⁷⁷

649. At the heart of Purdue’s public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation is in virtually all of Purdue’s recent pronouncements in response to the opioid epidemic.

650. Touting the benefits of ADF opioids, Purdue’s website asserts: “[W]e are acutely aware of the public health risks these powerful medications create . . . That’s why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid

²⁷⁷ Purdue, *Setting The Record Straight On OxyContin’s FDA-Approved Label* (May 5, 2016), <http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontin-fda-approved-label/>; Purdue, *Setting The Record Straight On Our Anti-Diversion Programs* (July 11, 2016), <http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/>.

abuse and misuse”²⁷⁸ Purdue’s statement on “Opioids Corporate Responsibility” likewise states that “[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with . . . communities, law enforcement, and government.”²⁷⁹ And, responding to criticism of Purdue’s failure to report suspicious prescribing to government regulatory and enforcement authorities, the website similarly proclaims that Purdue “ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion.”²⁸⁰

651. These public pronouncements create the false impression that Purdue is proactively working with law enforcement and government authorities nationwide to root out drug diversion, including the illicit prescribing that can lead to diversion. It aims to distance Purdue from its past conduct in deceptively marketing opioids and make its current marketing seem more trustworthy and truthful.

652. Public statements by the Defendants and their associates created the false and misleading impression to regulators, prescribers, and the public that the Defendants rigorously carried out their legal duties, including their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and further created the false impression that these Defendants also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

²⁷⁸ Purdue website, *Opioids With Abuse-Deterrent Properties*, <http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/> (last accessed Aug. 1, 2018).

²⁷⁹ *Id.*

²⁸⁰ Purdue, *Setting The Record Straight On Our Anti-Diversion Programs* (July 11, 2016), available at <http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/>. Contrary to its public statements, Purdue seems to have worked behind the scenes to push back against law enforcement.

B. The Marketing Defendants' Unlawful Failure To Prevent Diversion And Monitor, Report, And Prevent Suspicious Orders

653. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants were also legally required of the Marketing Defendants. Like the Distributor Defendants, the Marketing Defendants were required to register with state agencies and the DEA to manufacture and distribute Schedule II controlled substances, like prescription opioids. See 21 U.S.C. § 823(a).

654. Additionally, as “registrants” under Section 823, the Marketing Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. 21 C.F.R. § 1301.74; *see also* 21 C.F.R. § 1301.02 (“Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.”); 21 C.F.R. § 1300.01 (“Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).”)

655. Defendants violated both state law and the federal Controlled Substances Act in failing to report suspicious orders of opioid pain medications. Defendants violated state law in failing to maintain effective controls against the diversion of opioids into other than legitimate medical channels. Defendants also violated state law in failing to operate a system to stop orders which is flagged or should have been flagged as suspicious.

656. Like the Distributor Defendants, the Marketing Defendants breached these duties.

657. The Marketing Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Marketing Defendants engaged in the practice of paying “chargebacks” to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the

manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Marketing Defendants knew – just as the Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Marketing Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

658. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.²⁸¹

659. In the press release accompanying the settlement, the Department of Justice stated: “[Mallinckrodt] did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone.” . . . “Mallinckrodt’s actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . .”²⁸²

660. Among the allegations resolved by the settlement, the government alleged

²⁸¹ See Press Release, U.S. Dep’t of Justice, Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders>.

²⁸² *Id.*

“Mallinckrodt failed to design and implement an effective system to detect and report ‘suspicious orders’ for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders.”²⁸³

661. The Memorandum of Agreement entered into by Mallinckrodt (“2017 Mallinckrodt MOA”) avers “[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA.”²⁸⁴ Mallinckrodt further stated that it “recognizes the importance of the prevention of diversion of the controlled substances they manufacture” and agreed that it would “design and operate a system that meets the requirements of 21 C.F.R. § 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product.” Mallinckrodt specifically agreed “to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers.”

662. The 2017 Mallinckrodt MOA further details the DEA’s allegations regarding Mallinckrodt’s failures to fulfill its legal duties as an opioid manufacturer:

- a. With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt’s alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt’s alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. §

²⁸³ *Id.*

²⁸⁴ Administrative Memorandum of Agreement between the U.S. Dep’t of Justice, the Drug Enf’t Admin., and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (July 10, 2017), <https://www.justice.gov/usao-edmi/press-release/file/986026/download> (“2017 Mallinckrodt MOA”).

1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to: conduct adequate due diligence of its customers;

- b. Detect and report to the DEA orders of unusual size and frequency;
- c. Detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:
 - i. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,
 - ii. orders that purchased a disproportionate amount of substance which is most often abused compared to other products, and
 - iii. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;
- d. Use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and
- e. Take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.²⁸⁵

663. Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007." Mallinckrodt further agreed that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and would "design and operate a system that meets the requirements

²⁸⁵ *Id.* at 2-3.

of 21 C.F.R. 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers.”²⁸⁶

664. Mallinckrodt acknowledged that “[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to ‘downstream’ registrants.” Mallinckrodt agreed that, from this data, it would “report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion.”²⁸⁷

665. The same duties imposed by federal law on Mallinckrodt were imposed upon all Marketing Defendants.

666. The same business practices utilized by Mallinckrodt regarding “charge backs” and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including the other Marketing and Distributor Defendants.

667. Through, *inter alia*, the charge back data, the Marketing Defendants could monitor suspicious orders of opioids.

668. The Marketing Defendants failed to monitor, report, and halt suspicious orders of opioids as required by federal and state law.

669. The Marketing Defendants’ failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

²⁸⁶ *Id.* at 3-4.

²⁸⁷ *Id.* at 5.

670. The Marketing Defendants have misrepresented their compliance with federal and state law.

671. The wrongful actions and omissions of the Marketing Defendants that caused the diversion of opioids and which were a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiffs' allegations of Defendants' unlawful acts below.

672. The Marketing Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids throughout the United States.

C. The Distributor Defendants' Unlawful Distribution of Opioids

673. The Distributor Defendants owe a duty under, *inter alia*, state common law and statutory law to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted. The Distributor Defendants also owe a duty under federal law (21 U.S.C. § 823, 21 CFR § 1301.74) to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted.

674. The foreseeable harm from a breach of these duties was the medical, social, and financial consequences rippling through society, arising from the abuse of diverted opioids for nonmedical purposes.

675. Each Distributor Defendant repeatedly and purposefully breached its duties under state law. Such breaches are a direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes, with the resultant medical and financial damages.

676. For over a decade, all the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Rather, as described below, Defendants are subject to various duties to report the quantity of Schedule II controlled substances in order to monitor such substances and prevent oversupply and diversion into the illicit market.

677. The unlawful diversion of prescription opioids is a direct and proximate cause of the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality, with social and financial costs borne by, among others, individuals, families and hospitals.

678. The Distributor Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid epidemic and causing the damages alleged herein.

1. The Distributor Defendants Breached Their Duties

679. Opioids are a controlled substance. These “Schedule II” drugs are controlled substances with a “high potential for abuse.” 21 U.S.C. §§ 812(b), 812(2)(A)-(C).

680. Each Distributor Defendant was required to register with the DEA, pursuant to the federal Controlled Substance Act. *See* 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100. Each Distributor Defendant is a “registrant” as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme.

681. Each Distributor Defendant has an affirmative duty under federal law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain

“effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.” 21 U.S.C. §§ 823(b)(1).

682. Federal regulations impose a non-delegable duty upon wholesale drug distributors to “design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. § 1301.74(b).

683. “Suspicious orders” include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. *See* 21 CFR § 1301.74(b). These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor’s responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor’s customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

684. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg.

36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, all flagged orders must be reported. Id.

685. These prescription drugs are regulated for the purpose of providing a “closed” system intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.²⁸⁸

686. Because distributors are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on them to maintain effective controls to prevent diversion of controlled substances.

687. The sheer volume of prescription opioids distributed to pharmacies in various areas, and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted, was excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.²⁸⁹

688. As the DEA advised the Distributor Defendants in a letter dated September 27, 2006, wholesale distributors are “one of the key components of the distribution chain. If the closed system is to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This

²⁸⁸ See 1970 U.S.C.C.A.N. 4566, 4571-72.

²⁸⁹ *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy*, Nos. 219 and 5195, 77 Fed. Reg. 62,316, 62,322 (2012)).

responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.”²⁹⁰

689. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders.²⁹¹

690. The DEA’s September 27, 2006 letter also warned the Distributor Defendants that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, in addition to reporting suspicious orders, has a “statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.”²⁹² The letter also instructs that “distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.”²⁹³ The DEA warns that “even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.”

691. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.²⁹⁴ This letter reminds the Distributor Defendants of their statutory and regulatory duties

²⁹⁰ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Sept. 27, 2006) (hereinafter “Rannazzisi Letter”) (“This letter is being sent to every commercial entity in the United States registered with the Drug Enf’t Admin. (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.”), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

²⁹¹ See Brief for HDMA and NACDS, 2016 WL 1321983, at *4 (“[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy’s placement of unusually frequent or large orders.”).

²⁹² Rannazzisi Letter, at 2.

²⁹³ *Id.* at 1.

²⁹⁴ *Id.* at 2.

to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.”²⁹⁵ The letter further explains:

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., “excessive purchase report” or “high unity purchases”) does not meet the regulatory requirement to report suspicious orders.

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive.

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant’s DEA Certificate of Registration.²⁹⁶

692. Finally, the DEA letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and “some criteria to use when determining whether an order is suspicious.”²⁹⁷

693. The Distributor Defendants admit that they “have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”²⁹⁸

²⁹⁵ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug. Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

²⁹⁶ *Id.*

²⁹⁷ *Id.*

²⁹⁸ See Amicus Curiae Brief of Healthcare Distribution Mgmt. Ass’n in Support of App. Cardinal Health, Inc., *Cardinal Health, Inc. v. U.S. Dep’t of Justice*, No. 12- 5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *10 (hereinafter “Brief of HDMA in Support of Cardinal”).

694. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association (now known as the HDA, a front group of the Defendants, discussed below), the trade association of pharmaceutical distributors, explain that distributors are “[a]t the center of a sophisticated supply chain” and therefore “are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers.” The guidelines set forth recommended steps in the “due diligence” process, and note in particular: If an order meets or exceeds a distributor’s threshold, as defined in the distributor’s monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.²⁹⁹

695. The FTC has recognized the unique role of distributors. Since their inception, Distributor Defendants have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, as wholesalers, Distributor Defendants also offer their pharmacy, or dispensing, customers a broad range of added services. For example, Distributor Defendants offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory carrying costs. Distributor Defendants are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software

²⁹⁹ Healthcare Distribution Mgmt. Ass’n (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App’x B).

assistance and other database management support. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal, Inc. and Bergen Brunswig Corp.). As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, Distributor Defendants have a unique insight into the ordering patterns and activities of their dispensing customers.

696. The DEA also repeatedly reminded the Defendants of their obligations to report and decline to fill suspicious orders. Responding to the proliferation of pharmacies operating on the internet that arranged illicit sales of enormous volumes of opioids to drug dealers and customers, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes. Each of the Distributor Defendants attended at least one of these conferences. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion.

697. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers from which the Distributor Defendants knew prescription opioids were likely to be diverted.

698. Each Distributor Defendant owes a duty to monitor, detect and refuse suspicious orders of prescription opioids, to report suspicious orders of prescription opioids and to prevent the diversion of prescription opioids into illicit markets.

699. The Distributor Defendants failed to report “suspicious orders,” which the Distributor Defendants knew were likely to be diverted, to the relevant governmental authorities.

700. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern, and/or orders of unusual frequency, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted.

701. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted.

702. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

703. The Distributor Defendants breached their duty to “design and operate a system to disclose to the registrant suspicious orders of controlled substances” and failed to inform the authorities, including the DEA, of suspicious orders when discovered in violation of their duties under state law.

704. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific, and industrial channels.³⁰⁰

705. The laws at issue here concerning the sale and distribution of controlled substances are also the public safety statutes and regulations of states in which Plaintiffs’ hospitals operate.

706. The Distributor Defendants’ violations of public safety statutes constitute *prima facie* evidence of negligence under state law.

³⁰⁰ See *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

707. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants refuse to abide by the duties imposed by state law which are required to legally acquire and maintain a license to distribute prescription opiates.

708. The Distributor Defendants acted with actual malice in breaching their duties, i.e., they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

709. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

a. Cardinal

710. To date, Cardinal has paid a total of \$98 million in fines and other amounts involving multiple DEA and various state actions relating to its improper management and distribution of opioids to pharmacies across the United States.

711. In 2008, Cardinal paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven warehouses around the United States (the "2008 Cardinal Settlement Agreement").³⁰¹ These allegations included failing to report to the DEA thousands of

³⁰¹ Settlement and Release Agreement and Administrative Memorandum of Agreement (Sept. 30, 2008), a cached version is *available at* https://webcache.googleusercontent.com/search?q=cache:O7Te0HbVfpIJ:https://www.dea.gov/divisions/hq/2012/cardinal_agreement.pdf+&cd=2&hl=en&ct=clnk&gl=us; Press Release, U.S. Att'y Office, Dist. of Colo., Cardinal Health Inc., Agrees to Pay \$34 Million to Settle Claims that it Failed to Report Suspicious Sales of Widely-Abused Controlled Substances (Oct. 2, 2008), https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.

suspicious orders of hydrocodone that Cardinal then distributed to pharmacies that filled illegitimate prescriptions originating from rogue Internet pharmacy websites.³⁰²

712. In connection with the 2008 Cardinal Settlement Agreement, the DEA stated that “[d]espite [its] repeated attempts to educate Cardinal on diversion awareness and prevention, Cardinal engaged in a pattern of failing to report blatantly suspicious orders for controlled substances filled by its distribution facilities located throughout the United States.”³⁰³ The DEA concluded that “Cardinal’s conduct allowed the ‘diversion’ of millions of dosage units of hydrocodone from legitimate to non-legitimate channels.”³⁰⁴

713. As part of the 2008 Cardinal Settlement Agreement, Cardinal agreed to “maintain a compliance program designed to detect and prevent diversion of controlled substances as required by the CSA and applicable DEA regulations.”³⁰⁵ However, in 2012, the DEA issued an “immediate suspension order,” suspending Cardinal’s registration with respect to Cardinal’s drug distribution facility in Lakeland, Florida. That order stated that “Despite the [2008 Cardinal Settlement Agreement], the specific guidance provided to Cardinal by DEA, and despite the public information readily available regarding the oxycodone epidemic, Cardinal has failed to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of [the CSA].”³⁰⁶ For example, from “2008-2009, Cardinal’s sales to its top four retail pharmacies [in the State of Florida] increased approximately

³⁰² *Id.*

³⁰³ U.S. Att’y Office, Dist. of Colo., *Cardinal Health Inc. Agrees to Pay \$34 Million to Settle Claims that It Failed to Report Suspicious Sales of Widely-Abused Controlled Substances* (Oct. 2, 2008), https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.

³⁰⁴ *Id.*

³⁰⁵ *Cardinal Health, Inc. v. Eric Holder, Jr., Att’y Gen., D.D.C.* Case No. 12-185, ECF No. 3-4, at ¶ 2 (Feb. 3, 2012).

³⁰⁶ *Id.* at ¶ 3.

803%. From 2009 to 2010, Cardinal's sales to its top four retail pharmacies [in the State of Florida] increased 162%.”³⁰⁷

714. In 2012, Cardinal reached another settlement with the DEA relating to its failure to “conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels” resulting in systemic opioid diversion in its Florida distribution center (the “2012 Cardinal Settlement Agreement”).³⁰⁸ Cardinal’s Florida center received a two-year license suspension for supplying more than 12 million dosage units to only four area pharmacies, nearly fifty times as much oxycodone as it shipped to the rest of Florida and an increase of 241% in only two years.³⁰⁹ The DEA found that Cardinal’s own investigator warned Cardinal against selling opioids to these pharmacies, but that Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacies.³¹⁰ Instead, Cardinal’s opioid shipments to the pharmacies increased.³¹¹

715. In the 2012 Cardinal Settlement Agreement, Cardinal agreed that it had (i) failed to maintain effective controls against the diversion of controlled substances, including failing to conduct meaningful due diligence to ensure that controlled substances were not diverted; (ii) failed to detect and report suspicious orders of controlled substances as required by the CSA, on or before

³⁰⁷ *Id.* at ¶ 4.

³⁰⁸ Administrative Memorandum of Agreement (May 14, 2012), https://www.dea.gov/divisions/hq/2012/cardinal_agreement.pdf (last accessed August 1, 2018); Press Release, Drug Enf’t Admin., DEA Suspends for Two Years Pharmaceutical Wholesale Distributor’s Ability to Sell Controlled Substances from Lakeland, Florida Facility (May 15, 2012), <https://www.dea.gov/pubs/pressrel/pr051512.html>.

³⁰⁹ *Id.*

³¹⁰ *Id.*

³¹¹ *Id.*

May 14, 2012; and (iii) failed to adhere to the provisions of the 2008 Cardinal Settlement Agreement.³¹²

716. In December 2016, Cardinal again settled charges that it had violated the CSA by failing to prevent diversion of oxycodone for illegal purposes, this time for \$44 million (the “2016 Cardinal Settlement Agreement”).³¹³ The settlement covered DEA allegations that Cardinal had failed to report suspicious orders across Washington, Maryland, New York, and Florida.³¹⁴ The same Florida distribution center at the heart of the 2012 settlement was again implicated in this case.³¹⁵ The settlement also covered a Cardinal subsidiary, Kinray, LLC, which failed to report a single suspicious order despite shipping oxycodone and hydrocodone to more than 20 New York-area pharmacy locations that placed unusually high orders of controlled substances at an unusually frequent rate.³¹⁶

b. AmerisourceBergen

717. AmerisourceBergen has paid \$16 million in settlements and had certain licenses revoked as a result of allegations related to the diversion of prescription opioids.

718. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies.³¹⁷ Over the course of one year, AmerisourceBergen had distributed 3.8

³¹² Administrative Memorandum of Agreement (May 14, 2012), https://www.dea.gov/divisions/hq/2012/cardinal_agreement.pdf (last accessed August 1, 2018).

³¹³ U.S. Att'y Office, Dist. of Md., *Cardinal Health Agrees to \$44 Million Settlement for Alleged Violations of Controlled Substances Act* (Dec. 23, 2016) <https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act>.

³¹⁴ *Id.*

³¹⁵ *Id.*

³¹⁶ *Id.*

³¹⁷ Press Release, Drug Enf't Admin., *DEA Suspends Orlando Branch of Drug Company from Distributing Controlled Substances* (Apr. 24, 2007), <https://www.dea.gov/divisions/mia/2007/mia042407p.html>.

million dosage units of hydrocodone to “rogue pharmacies.”³¹⁸ The DEA suspended AmerisourceBergen’s registration after determining that “the continued registration of this company constitutes an imminent danger to public health and safety.”³¹⁹

719. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of particular controlled substances into non-medically necessary channels.³²⁰

2. The Distributor Defendants Have Sought to Avoid and Have Misrepresented Their Compliance with Their Legal Duties

720. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under state law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public regarding the Distributor Defendants’ compliance with their legal duties.

721. Distributor Defendants have refused to recognize any duty beyond reporting suspicious orders. In *Masters Pharm., Inc. v. Drug Enf’t Admin.*, 861 F.3d 206 (D.C. Cir. 2017), the Healthcare Distribution Management Association, n/k/a HDA, a trade association run by the Distributor Defendants, and the National Association of Chain Drug Stores (“NACDS”), an association of the National Retail Pharmacies (and similar persons), submitted amicus briefs regarding the legal duty of wholesale distributors. Denying – inaccurately – the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows:

- a. The Associations complained that the “DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled.”³²¹

³¹⁸ *Id.*

³¹⁹ *Id.*

³²⁰ Jeff Overley, *AmerisourceBergen Subpoenaed by DEA Over Drug Diversion*, Law360.com (Aug. 9, 2012), available at <https://www.law360.com/articles/368498/amerisourcebergen-subpoenaed-by-dea-over-drug-diversion>.

³²¹ Brief for HDMA and NACDS, 2016 WL 1321983, at *4–5.

- b. The Associations argued that, “DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications.”³²²
- c. The Associations alleged (inaccurately) that nothing “requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious.”³²³
- d. The Associations complained that the purported “practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties.”³²⁴
- e. The Associations alleged (inaccurately) that “DEA’s regulations [] sensibly impose [] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders.”³²⁵
- f. Also inaccurately, the Associations argued that, “[i]mposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA’s demands.”³²⁶

722. The positions taken by the trade groups is emblematic of the position taken by the

Distributor Defendants in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs.³²⁷

³²² *Id.* at *8 (citations and quotation marks omitted).

³²³ *Id.* at *14.

³²⁴ *Id.* at *22.

³²⁵ *Id.* at *24–25

³²⁶ *Id.* at 26.

³²⁷ See Brief of HDMA in Support of Cardinal, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry “does not know the rules of the road because” they claim (inaccurately) that the “DEA has not adequately explained them”).

723. The Court of Appeals for the District of Columbia Circuit recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. In *Masters Pharmaceuticals*, the Court upheld the revocation of Masters Pharmaceutical's license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors must "decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order." Masters Pharmaceutical was in violation of legal requirements because it failed to conduct necessary investigations and filled suspicious orders. A distributor's investigation must dispel all the red flags giving rise to suspicious circumstance prior to shipping a suspicious order. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above), that, allegedly, the DEA had created or imposed new duties.

724. Because of the Distributor Defendants' refusals to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.³²⁸ As noted above, the Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.³²⁹ These actions include the following:

- a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled

³²⁸ Evaluation and Inspections Div., Off. of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* (May 2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

³²⁹ *Id.*

- substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Auburn, Washington Distribution Center (“Auburn Facility”) for failure to maintain effective controls against diversion of hydrocodone;
 - c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of hydrocodone;
 - d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Swedesboro, New Jersey Distribution Center (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone;
 - e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;
 - f. On September 30, 2008, Cardinal entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia (“McDonough Facility”), Valencia, California (“Valencia Facility”) and Denver, Colorado (“Denver Facility”);
 - g. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of oxycodone; and
 - h. On December 23, 2016, Cardinal agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center.

725. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry,

pressured the U.S. Department of Justice to “halt” prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a “sharp drop in enforcement actions” and the passage of the “Ensuring Patient Access and Effective Drug Enforcement Act” which, ironically, raised the burden for the DEA to revoke a distributor’s license from “imminent harm” to “immediate harm” and provided the industry the right to “cure” any violations of law before a suspension order can be issued.³³⁰

726. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

727. For example, a Cardinal executive claimed that it uses “advanced analytics” to monitor its supply chain and represented that it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”³³¹ Given the

³³⁰ See Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, WASHINGTON POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.2f757833e3c4; Lenny Bernstein & Scott Higham, *Investigations: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, WASHINGTON POST (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.7007bf2b9455; Eric Eyre, *DEA Agent: “We Had No Leadership” in WV Amid Flood of Pain Pills*, CHARLESTON GAZETTE-MAIL (Feb. 18, 2017), https://www.wvgazettemail.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article_928e9bcd-e28e-58b1-8e3f-f08288f539fd.html.

³³¹ Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No One Was Doing Their Job,”* WASHINGTON POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.a5f051722a7a.

sales volumes and the company's history of violations, this executive was either not telling the truth, or, if Cardinal had such a system, it ignored the results.

728. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiffs now assert.

729. Meanwhile, the opioid epidemic rages unabated in the United States.

730. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

731. The wrongful actions and omissions of the Distributor Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiffs' allegations of Defendants' unlawful acts below.

732. The Distributor Defendants have abandoned their duties imposed under state law, taken advantage of a lack of adequate law enforcement, and abused the privilege of distributing controlled substances.

D. The National Retail Pharmacies Were On Notice of and Contributed to Illegal Diversion of Prescription Opioids

733. National retail pharmacy chains earned enormous profits by flooding the country with prescription opioids.³³² They were keenly aware of the oversupply of prescription opioids

³³² Plaintiffs' allegations of wrongdoing are pointing to the National Retail Pharmacies not the pharmacy industry who in general serve a vital healthcare function in the US.

through the extensive data and information they developed and maintained as both distributors and dispensaries. Yet, instead of taking any meaningful action to stem the flow of opioids into communities, they continued to participate in the oversupply and profit from it.

734. Each of the National Retail Pharmacies does substantial business throughout the United States. This business includes the distribution and dispensing of prescription opioids.

735. Data shows the National Retail Pharmacies distributed and dispensed substantial quantities of prescription opioids, including fentanyl, hydrocodone, and oxycodone in Ohio as in other states. The National Retail Pharmacies failed to take meaningful action to stop this diversion despite their knowledge of it, and contributed substantially to the diversion problem.

736. The National Retail Pharmacies developed and maintained extensive data on opioids they distributed and dispensed. Through this data, National Retail Pharmacies had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in communities throughout the country, and in the states in which Plaintiffs operate. They used the data to evaluate their own sales activities and workforce. On information and belief, the National Retail Pharmacies also provided Defendants with data regarding, inter alia, individual doctors in exchange for rebates or other forms of consideration. The National Retail Pharmacies' data is a valuable resource that they could have used to help stop diversion, but failed to do so.

1. The National Retail Pharmacies Have a Duty to Prevent Diversion

737. Each participant in the supply chain of opioid distribution, including the National Retail Pharmacies, is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring and reporting suspicious activity.

738. The National Retail Pharmacies, like manufacturers and other distributors, are registrants under the CSA. 21 C.F.R. § 1301.11. Under the CSA, pharmacy registrants are required to “provide effective controls and procedures to guard against theft and diversion of

controlled substances.” See 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, “[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.” Because pharmacies themselves are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

739. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion.

740. Suspicious pharmacy orders include orders unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern and/or orders of unusual frequency and duration, among others.

741. Additional types of suspicious orders include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look “too good” or where the prescriber’s handwriting is too legible; (5) prescriptions with quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies.

742. Suspicious pharmacy orders are red flags for if not direct evidence of diversion.

743. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the National Retail Pharmacies themselves. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing.

744. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

745. Despite their legal obligations as registrants under the CSA, the National Retail Pharmacies allowed widespread diversion to occur—and they did so knowingly. They knew they made money by filling prescriptions, not by not filling descriptions. They knew they made money by making it easy for doctors to refer patients with drug prescriptions to them to fill, not by making it difficult for doctors to refer patients to them to fill descriptions.

746. Performance metrics and prescription quotas adopted by the National Retail Pharmacies for their retail stores contributed to their failure. For instance, under CVS's Metrics System, for example, pharmacists are directed to meet high goals that make it difficult, if not impossible, to comply with applicable laws and regulations. There is no measurement for pharmacy accuracy or customer safety. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. The result is both deeply troubling and entirely predictable: opioids flowed out of National Retail Pharmacies and into communities throughout the country. The policies remained in place even as the epidemic raged.

747. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that this problem was compounded by the National Retail Pharmacies' failure to adequately train their pharmacists and pharmacy technicians on how to

properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when suspicious circumstances are present, including when prescriptions are procured and pills supplied for the purpose of illegal diversion and drug trafficking.

748. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that the National Retail Pharmacies also failed to adequately use data available to them to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids, or to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

749. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that the National Retail Pharmacies failed to analyze: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

750. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that the National Retail Pharmacies also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

751. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that the National Retail Pharmacies also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

752. The National Retail Pharmacies were, or should have been, fully aware that the quantity of opioids being distributed and dispensed by them was untenable, and in many areas patently absurd; yet, they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

2. Multiple Enforcement Actions against the National Retail Pharmacies Confirms their Compliance Failures

753. The National Retail Pharmacies have long been on notice of their failure to abide by state and federal law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the National Retail Pharmacies have been repeatedly penalized for their illegal prescription opioid practices. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the National Retail Pharmacies.

a. CVS

754. CVS is one of the largest companies in the world, with annual revenue of more than \$150 billion. According to news reports, it manages medications for nearly 90 million customers at 9,700 retail locations. CVS could be a force for good in connection with the opioid crisis, but like other Defendants, CVS sought profits over people.

755. CVS is a repeat offender; the company has paid fines totaling over \$40 million as the result of a series of investigations by the DEA and the DOJ. It nonetheless treated these fines

as the cost of doing business and has allowed its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require, and to continue violating its recordkeeping and dispensing obligations under the CSA.

756. As recently as July 2017, CVS entered into a \$5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.³³³

757. This fine was preceded by numerous others throughout the country.

758. In February 2016, CVS paid \$8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA and filling prescriptions with no legitimate medical purpose.³³⁴

759. In October 2016, CVS paid \$600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.³³⁵

760. In September 2016, CVS entered into a \$795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the

³³³ Press Release, U.S. Attorney's Office E. Dist. of Cal., *CVS Pharmacy Inc. Pays \$5M to Settle Alleged Violations of the Controlled Substance Act*, U.S. Dep't of Just. (July 11, 2017), <https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc-pays-5m-settle-alleged-violationscontrolled-substance-act>.

³³⁴ Press Release, U.S. Attorney's Office Dist. of Md., *United States Reaches \$8 Million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances*, U.S. Dep't of Just. (Feb. 12, 2016), <https://www.justice.gov/usao-md/pr/united-states-reaches-8-millionsettlement-agreement-cvs-unlawful-distribution-controlled>.

³³⁵ Press Release, U.S. Attorney's Office Dist. of Conn., *CVS Pharmacy Pays \$600,000 to Settle Controlled Substances Act Allegations*, U.S. Dep't of Just. (Oct. 20, 2016), <https://www.justice.gov/usao-ct/pr/cvs-pharmacy-pays-600000-settle-controlled-substances-actallegations>.

state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.³³⁶

761. In June 2016, CVS agreed to pay the DOJ \$3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014.³³⁷

762. In August 2015, CVS entered into a \$450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.³³⁸

763. In May 2015, CVS agreed to pay a \$22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, “based on prescriptions that had not been issued for legitimate medical

³³⁶ Dialynn Dwyer, *CVS will pay \$795,000, strengthen policies around dispensing opioids in agreement with state*, Boston.com (Sept. 1, 2016), <https://www.boston.com/news/localnews/2016/09/01/cvs-will-pay-795000-strengthen-policies-around-dispensing-opioids-inagreement-with-state>.

³³⁷ Press Release, U.S. Attorney's Office Dist. of Mass., *CVS to Pay \$3.5 Million to Resolve Allegations that Pharmacists Filled Fake Prescriptions*, U.S. Dep't of Just. (June 30, 2016), <https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filledfake-prescriptions>.

³³⁸ Press Release, U.S. Attorney's Office Dist. of R.I., Drug Diversion Claims Against CVS Health Corp. Resolved With \$450,000 Civil Settlement, U.S. Dep't of Just. (Aug. 10, 2015), <https://www.justice.gov/usao-ri/pr/drug-diversion-claims-against-cvs-health-corp-resolved-450000-civil-settlement>.

purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need.”³³⁹

764. In September 2014, CVS agreed to pay \$1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.³⁴⁰

765. In August 2013, CVS was fined \$350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.³⁴¹

766. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.³⁴²

b. Walgreens

767. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than \$118 billion. According to its website, Walgreens

³³⁹ Press Release, U.S. Attorney’s Office M. Dist. of Fla., United States Reaches \$22 Million Settlement Agreement with CVS For Unlawful Distribution of Controlled Substances, U.S. Dep’t of Just. (May 13, 2015), <https://www.justice.gov/usao-mdfl/pr/united-states-reaches-22-million-settlement-agreement-cvs-unlawful-distribution>.

³⁴⁰ Patrick Danner, H-E-B, CVS Fined Over Prescriptions, San Antonio Express-News (Sept. 5, 2014), <http://www.expressnews.com/business/local/article/H-E-BCVSfined-over-prescriptions-5736554.php>.

³⁴¹ Andrew Knittle, *Oklahoma pharmacy board stays busy, hands out massive fines at times*, NewsOK (May 3, 2015), <http://newsok.com/article/5415840>.

³⁴² Press Release, U.S. Attorney’s Office W. Dist. of Okla., CVS to Pay \$11 Million To Settle Civil Penalty Claims Involving Violations of Controlled Substances Act, U.S. Dep’t of Just. (Apr. 3, 2013), <https://www.justice.gov/usao-wdok/pr/cvs-pay-11-million-settle-civil-penaltyclaims-involving-violations-controlled>.

operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

768. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—\$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black market sales.³⁴³

769. As part of the settlement, Walgreens admitted that it failed to uphold its obligations as a DEA registrant regarding the above-described conduct.³⁴⁴

770. The settlement resolved investigations into and allegations of CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

771. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.³⁴⁵

772. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens corporate officers not only turned a blind eye,

³⁴³ Press Release, U.S. Attorney's Office S. Dist. of Fla., *Walgreens Agrees to Pay a Record Settlement of \$80 Million for Civil Penalties Under the Controlled Substances Act*, U.S. Dep't of Just. (June 11, 2013), <https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-recordsettlement-80-million-civil-penalties-under-controlled>.

³⁴⁴ *Id.*

³⁴⁵ Order to Show Cause and Immediate Suspension of Registration, *In the Matter of Walgreens Co.* (Drug Enf't Admin. Sept. 13, 2012).

but provided pharmacists with incentives through a bonus program that compensated them based on the number of prescriptions filled at the pharmacy. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that “if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance,” underscoring Walgreens’ attitude that profit outweighed compliance with the CSA or the health of communities.³⁴⁶

773. Defendant Walgreens’ settlement with the DEA stemmed from the DEA’s investigation into Walgreens’ distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens’ corporate headquarters pushed to increase the number of oxycodone sales to Walgreens’ Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.³⁴⁷

774. The six retail pharmacies in Florida that received the suspicious drug shipments from the Jupiter Distribution Center, in turn, filled customer prescriptions that they knew or should have known were not for legitimate medical use.³⁴⁸

³⁴⁶ *Id.*

³⁴⁷ *Id.*

³⁴⁸ *Id.*

775. Walgreens has also settled with a number of state attorneys general, including West Virginia (\$575,000) and Massachusetts (\$200,000).³⁴⁹

776. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.

777. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and didn't use sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay \$200,000 and follow certain procedures for dispensing opioids.³⁵⁰

c. Rite Aid

778. With approximately 4,600 stores in 31 states and the District of Columbia, Rite Aid is the largest drugstore chain on the East Coast and the third-largest in the United States, with annual revenue of more than \$21 billion.

779. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined \$5 million in civil penalties for its violations of the CSA.³⁵¹

780. The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the CSA and federal

³⁴⁹ *Walgreens to pay \$200,000 settlement for lapses with opioids*, APhA (Jan. 25, 2017), <https://www.pharmacist.com/article/walgreens-pay-200000-settlement-lapses-opioids>.

³⁵⁰ *Id.*

³⁵¹ Press Release, Dep't of Just., *Rite Aid Corporation and Subsidiaries Agree to Pay \$5 Million in Civil Penalties to Resolve Violations in Eight States of the Controlled Substances Act*, U.S. Dep't of Just. (Jan. 12, 2009), <https://www.justice.gov/opa/pr/rite-aid-corporation-andsubsidiaries-agree-pay-5-million-civil-penalties-resolve-violations>.

regulations that lead to the diversion of prescription opioids in and around the communities of the Rite Aid pharmacies investigated. Rite Aid also failed to notify the DEA of losses of controlled substances in violation of 21 USC 842(a)(5) and 21 C.F.R 1301.76(b).³⁵²

781. Numerous state and federal drug diversion prosecutions have occurred in which prescription opioid pills were procured from National Retail Pharmacies. The allegations in this Complaint do not attempt to identify all these prosecutions, and the information above is merely by way of example.

782. The litany of state and federal actions against the National Retail Pharmacies demonstrate that they routinely, and as a matter of standard operation procedure, violated their legal obligations under the CSA and other laws and regulations that govern the distribution and dispensing of prescription opioids.

783. Throughout the country and in the states in which Plaintiffs operate, the National Retail Pharmacies were or should have been aware of numerous red flags of potential suspicious activity and diversion.

784. On information and belief, from the catbird seat of their retail pharmacy operations, the National Retail Pharmacies knew or reasonably should have known about the disproportionate flow of opioids throughout the stream of commerce nationwide, and the operation of “pill mills” that generated opioid prescriptions that, by their quantity or nature, were red flags for if not direct evidence of illicit supply and diversion. Additional information was provided by news reports, and state and federal regulatory actions, including prosecutions of pill mills in the area.

³⁵² *Id.*

785. On information and belief, the National Retail Pharmacies knew or reasonably should have known about the devastating consequences of the oversupply and diversion of prescription opioids, including spiking opioid overdose rates in the community.

786. On information and belief, because of (among others sources of information) regulatory and other actions taken against the National Retail Pharmacies directly, actions taken against others pertaining to prescription opioids obtained from their retail stores, complaints and information from employees and other agents, and the massive volume of opioid prescription drug sale data that they developed and monitored, the National Retail Pharmacies were well aware that their distribution and dispensing activities fell far short of legal requirements.

787. The National Retail Pharmacies' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have contributed significantly to the opioid crisis by enabling, and failing to prevent, the diversion of opioids.

VII. DEFENDANTS' UNLAWFUL CONDUCT AND BREACHES OF LEGAL DUTIES CAUSED THE HARM AND SUBSTANTIAL DAMAGE ALLEGED HEREIN

788. As the Marketing Defendants' efforts to expand the market for opioids increased so have the rates of prescription and sale of their products — and the rates of opioid-related substance abuse, hospitalization, and death among the people of the United States. The Distributor Defendants have continued to unlawfully ship these massive quantities of opioids.

789. There is a “parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes.”³⁵³

790. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.³⁵⁴

791. The epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”³⁵⁵

792. The increased abuse of prescription painkillers along with growing sales has contributed to a large number of overdoses and deaths.³⁵⁶

793. One doctor, for example in Ohio, was convicted of illegally distributing some 30,000 tablets of oxycodone, OxyContin, and Opana. In connection with sentencing, the U.S. Attorney explained that its enforcement efforts reflected that “[o]ur region is awash in opioids that have brought heartbreak and suffering to countless families.” Henry Schein delivered opioids directly to the office of this doctor, whom the Northern District of Ohio court has described as “selling 30,000 doses of poison into the community.”³⁵⁷ In a separate civil suit, the same prescriber reached a consent judgment in a civil suit alleging that he was purchasing hydrocodone/APAP tablets (hydrocodone and acetaminophen), from Henry Schein on as many as fourteen separate

³⁵³ See Richard C. Dart et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241-248 (2015), DOI: 10.1056/NEJMsa1406143, <http://www.nejm.org/doi/full/10.1056/NEJMsa1406143>.

³⁵⁴ See Volkow & McLellan.

³⁵⁵ See Califf et al..

³⁵⁶ See Press Release, Centers for Disease Control and Prevention, U.S. Dep’t of Health and Human Servs.

³⁵⁷ Eric Heisig, *Former Akron-Area Doctor Sentenced to 63 Months in Prison for Doling Out Painkillers*, Cleveland.com (Mar. 16, 2015), https://www.cleveland.com/court-justice/index.ssf/2015/03/former_akron-area_doctor_sente.html.

dates within a one-year period, and, subsequently dispensed 11,500 hydrocodone tablets without maintaining purchase and dispensing records as required by the CSA.

794. As shown above, the opioid epidemic has escalated with devastating effects: substantial opiate-related substance abuse, hospitalization, and death that goes hand in hand with Defendants' increased distribution of opioids.

795. Because of the well-established relationship between the use of prescription opioids and the use of non-prescription opioids, like heroin, the massive distribution of opioids by Defendants has caused the opioid epidemic to include heroin addiction, abuse, and death.

796. Defendants repeatedly and purposefully breached their duties under federal and state law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes and the foreseeable, inevitable financial burdens imposed on and incurred by hospitals and other health care providers.

797. The increased financial burdens on hospitals include, but are not limited to the following:

- a. Unreimbursed costs for providing healthcare and medical care, additional therapeutic, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;
- b. Costs associated with patient counseling with respect to pain management, necessitated by overprescribing to the general population and dissemination of false and misleading information to prospective patients and others; as hospitals and other providers question their patients' self-reporting, it necessitates further steps to be taken in all phases of treatment and counseling;
- c. Unreimbursed costs of opioids purchased by hospitals themselves, which were direct targets of the Defendants' marketing campaigns;
- d. Unreimbursed costs of prescription drugs used to treat addiction;
- e. Costs of training additional personnel in the proper treatment of drug overdoses;

- f. Costs associated with obtaining and training staff in the application of naloxone—an opioid antagonist used to block the deadly effects of opioids in the context of overdose;
- g. Additional unreimbursed costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;
- h. Unreimbursed Costs for providing treatment of infants born with opioid-related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy.

798. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity, and mortality in the United States. This diversion and the epidemic are direct causes of foreseeable harm to Plaintiffs.

799. Defendants' unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Plaintiffs seek relief.

VIII. CONSPIRACY ALLEGATIONS

800. The Defendants conspired to engage in the wrongful conduct complained of herein and intended to benefit both independently and jointly from their wrongful conduct.

A. Conspiracy Among the Purdue Defendants

801. The Purdue Defendants agreed among themselves to cause Purdue and related business entities to (1) promote the use of opioids for the management of pain in order to mislead physicians, patients, health care providers such as hospitals, and health care payors through misrepresentations and omissions regarding the appropriate uses, risks, and safety of opioids in order to increase sales, revenue, and profit from their opioid products, and (2) increase the supply of opioids and fraudulently increase the quotas that governed the manufacture and supply of prescription opioids

802. In committing these wrongful acts, the Purdue Defendants have pursued, or joined in the pursuit of, a common course of conduct and have acted in concert with and conspired with one another in furtherance of their common plan or design. In addition to the wrongful conduct herein alleged as giving rise to primary liability, the Purdue Defendants further aided and abetted and/or assisted each other in breaching their respective duties.

803. The Purdue Defendants entered into a conspiracy, common enterprise, and/or common course of conduct. During all times relevant hereto, the Purdue Defendants, collectively and individually, initiated a course of conduct that was designed to and did misrepresent the properties of opioids, and facilitate the distribution of opioids. The Purdue Defendants did so in order to maximize the profits Purdue would receive from opioid sales. In furtherance of this plan, conspiracy, and course of conduct, the Purdue Defendants collectively and individually, took the actions set forth herein.

804. Each of the Purdue Defendants aided and abetted and rendered substantial assistance in the wrongs committed by their respective co-conspirators complained of herein. In taking such actions to substantially assist the commission of the wrongdoing complained of herein, each Purdue Defendant acted with knowledge of the primary wrongdoing, substantially assisted in the accomplishment of that wrongdoing, and was aware of his or her overall contribution to and furtherance of the wrongdoing.

B. Conspiracy Among the Marketing Defendants

805. The Marketing Defendants agreed among themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the management of pain in order to mislead physicians, patients, health care providers such as hospitals, and health

care payors through misrepresentations and omissions regarding the appropriate uses, risks, and safety of opioids in order to increase sales, revenue, and profit from their opioid products.

806. This interconnected and interrelated network relied on the Marketing Defendants' collective use of unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups developed and funded collectively by the Marketing Defendants and intended to mislead consumers and medical providers, such as hospitals, of the appropriate uses, risks, and safety of opioids.

807. The Marketing Defendants' collective marketing scheme to increase opioid prescriptions, sales, revenues and profits centered around the development, dissemination, and reinforcement of nine false propositions: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition dubbed "pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

808. The Marketing Defendants knew that none of these propositions are true.

809. Each Marketing Defendant worked individually and collectively to develop and actively promulgate these nine false propositions in order to mislead physicians, patients, and health care providers such as hospitals and healthcare payors regarding the appropriate uses, risks, and safety of opioids.

810. What is particularly remarkable about the Marketing Defendants' effort is the seamless method in which the Marketing Defendants joined forces to achieve their collective goal: to persuade consumers and medical providers, such as hospitals, of the safety of opioids, and to hide their actual risks and dangers. In doing so, the Marketing Defendants effectively built a new – and extremely lucrative – opioid marketplace for their select group of industry players.

811. The Marketing Defendants' unbranded promotion and marketing network was a wildly successful marketing tool that achieved marketing goals that would have been impossible to have been met by a single or even a handful of the network's distinct corporate members.

812. For example, the network members pooled their vast marketing funds and dedicated them to expansive and normally cost-prohibitive marketing ventures, such as the creation of Front Groups. These collaborative networking tactics allowed each Marketing Defendant to diversify its marketing efforts, all the while sharing any risk and exposure, financial and/or legal, with other Marketing Defendants.

813. The most unnerving tactic utilized by the Marketing Defendants' network was their unabashed mimicry of the scientific method of citing "references" in their materials. In the scientific community, cited materials and references are rigorously vetted by objective unbiased and disinterested experts in the field, and an unfounded theory or proposition would, or should, never gain traction.

814. Marketing Defendants put their own twist on the scientific method: they worked together to manufacture wide support for their unfounded theories and propositions involving opioids. Due to their sheer numbers and resources, the Marketing Defendants were able to create a false consensus through their materials and references.

815. An illustrative example of the Marketing Defendants' utilization of this tactic is the

wide promulgation of the Porter & Jick Letter, which declared the incidence of addiction “rare” for patients treated with opioids. The authors had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. These patients were not given long-term opioid prescriptions or provided opioids to administer to themselves at home, nor was it known how frequently or infrequently and in what doses the patients were given their narcotics. Rather, it appears the patients were treated with opioids for short periods of time under in-hospital doctor supervision.

816. Nonetheless, Marketing Defendants widely and repeatedly cited this letter as proof of the low addiction risk in connection with taking opioids despite the letter’s obvious shortcomings. Marketing Defendants’ egregious misrepresentations based on this letter included claims that less than one percent of opioid users became addicted.

817. Marketing Defendants’ collective misuse of the Porter & Jick Letter helped the opioid manufacturers convince patients and healthcare providers such as hospitals that opioids were not a concern. The enormous impact of Marketing Defendants’ misleading amplification of this letter was well documented in another letter published in the NEJM on June, 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and, in some cases, “grossly misrepresented.” In particular, the authors of this letter explained:

[W]e found that a five-sentence letter published in the Journal in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crises by helping to shape a narrative that allayed prescribers’ concerns about the risk of addiction associated with long-term opioid therapy...

By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, the Marketing Defendants committed overt acts in furtherance of their conspiracy.

C. Conspiracy Among the Marketing Defendants and the Supply Chain Defendants

818. In addition, and on an even broader level, all the Marketing Defendants and Supply Chain Defendants took advantage of the industry structure, including end-running its internal checks and balance, to their collective advantage. The Marketing Defendants and Supply Chain Defendants agreed among themselves to increase the supply of opioids and fraudulently increase the quotas that governed the manufacture and supply of prescription opioids. The Marketing Defendants and Supply Chain Defendants did so to increase sales, revenue, and profit from their opioid products.

819. The interaction and length of the relationships between and among the Marketing Defendants and Supply Chain Defendants reflect a deep level of interaction and cooperation between the Marketing Defendants and Supply Chain Defendants in a tightly knit industry. The Marketing and Supply Chain Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The Marketing Defendants and Supply Chain Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

820. The Marketing Defendants and Supply Chain Defendants collaborated to expand the opioid market in an interconnected and interrelated network in the following ways, as set forth more fully below including, for example, membership in the Healthcare Distribution Alliance.

821. The Marketing Defendants and Supply Chain Defendants utilized their membership in the HDA and other forms of collaboration to form agreements about their approach to their duties under the CSA to report suspicious orders. The Marketing Defendants and Supply Chain Defendants overwhelmingly agreed on the same approach – to fail to identify, report, or halt suspicious opioid orders, and fail to prevent diversion. The Marketing Defendants and Supply Chain Defendants' agreement to restrict reporting provided an added layer of insulation from DEA

scrutiny for the entire industry as the Marketing Defendants and Supply Chain Defendants were thus collectively responsible for each other's compliance with their reporting obligations. The Marketing Defendants and Supply Chain Defendants were aware, both individually and collectively, of the suspicious orders that flowed directly from the Marketing Defendants and Supply Chain Defendants' facilities.

822. The Marketing Defendants and Supply Chain Defendants knew that their own conduct could be reported by other Defendants and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, the Marketing Defendants and Supply Chain Defendants had an incentive to communicate with each other about the reporting or suspicious orders to ensure consistency in their dealings with DEA.

823. The Marketing Defendants and Supply Chain Defendants also worked together to ensure that the opioid quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

824. The desired consistency and collective end goal were achieved. The Marketing Defendants and Supply Chain Defendants achieved blockbuster profits through higher opioid sales by orchestrating the unimpeded flow of opioids.

IX. ADDITIONAL FACTS PERTAINING TO PUNITIVE DAMAGES

825. As set forth above, Defendants acted deliberately to increase sales of, and profits from, opioid drugs. The Marketing Defendants knew there was no support for their claims that addiction was rare, that addiction risk could be effectively managed, that signs of addiction were merely "pseudoaddiction," that withdrawal is easily managed, that higher doses pose no significant additional risks, that long-term use of opioids improves function, or that time-release or abuse-

deterrent formulations would prevent addiction or abuse. Nonetheless, they knowingly promoted these falsehoods in order to increase the market for their addictive drugs.

826. All of the Defendants, moreover, knew that large and suspicious quantities of opioids were being poured into communities throughout the United States. Despite this knowledge, Defendants took no steps to report suspicious orders, control the supply of opioids, or otherwise prevent diversion. Indeed, as described above, Defendants acted in concert together to maintain high levels of quotas for their products and to ensure that suspicious orders would not be reported to regulators.

827. Defendants' conduct was so willful and deliberate that it continued in the face of numerous enforcement actions, fines, and other warnings from state and local governments and regulatory agencies. Defendants paid their fines, made promises to do better, and continued on with their marketing and supply schemes. This ongoing course of conduct knowingly, deliberately, and repeatedly threatened and accomplished harm and risk of harm to public health and safety, and large-scale economic loss to communities, governments, families, communities, hospitals and health care providers across the country.

828. As all of the governmental actions against the Marketing Defendants and against all the Defendants show, Defendants knew that their actions were unlawful, and yet deliberately refused to change their practices because compliance with their legal obligations would have decreased their sales and their profits.

A. The Marketing Defendants Persisted in Their Fraudulent Scheme Despite Repeated Admonitions, Warnings, and Even Prosecutions

829. So determined were the Marketing Defendants to sell more opioids that they simply ignored multiple admonitions, warnings, and prosecutions, as described more fully below.

1. FDA Warnings to Janssen Failed to Deter Janssen's Misleading Promotion of Duragesic

830. On February 15, 2000, the FDA sent Janssen a letter concerning the dissemination of "homemade" promotional pieces that promoted the Janssen drug Duragesic in violation of the Federal Food, Drug, and Cosmetic Act. In a subsequent letter, dated March 30, 2000, the FDA explained that the "homemade" promotional pieces were "false or misleading because they contain misrepresentations of safety information, broaden Duragesic's indication, contain unsubstantiated claims, and lack fair balance." The March 30, 2000 letter detailed numerous ways in which Janssen's marketing was misleading.

831. The letter did not stop Janssen. On September 2, 2004, the U.S. Department of Health and Human Services ("HHS") sent Janssen a warning letter concerning Duragesic due to "false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated effectiveness claims for Duragesic," including, specifically, "suggesting that Duragesic has a lower potential for abuse compared to other opioid products." The September 2, 2004 letter detailed a series of unsubstantiated, false or misleading claims.

832. One year later, Janssen was still at it. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan N.V. The advisory noted that the FDA had been "examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch" and noted the possibility "that patients and physicians might be unaware of the risks" of using the fentanyl transdermal patch, which is a potent opioid analgesic approved only for chronic pain in opioid-tolerant patients that could not be treated by other drugs.

2. Governmental Action, Including Large Monetary Fines, Failed to Stop Cephalon From Falsely Marketing Actiq For Off-label Uses

833. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay \$425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil). According to a DOJ press release, Cephalon had trained sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs and funded CMEs to promote off-label uses.

834. Notwithstanding letters, an FDA safety alert, DOJ and state investigations, and the massive settlement, Cephalon has continued its deceptive marketing strategy.

3. FDA Warnings Did Not Prevent Cephalon from Continuing False and Off-Label Marketing of Fentora

835. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: “Fentora should not be used to treat any type of short-term pain.” Indeed, the FDA specifically denied Cephalon’s application, in 2008, to broaden the indication of Fentora to include treatment of non-cancer breakthrough pain and use in patients who were not already opioid-tolerant.

836. Flagrantly disregarding the FDA’s refusal to broaden the indication for Fentora, Cephalon nonetheless marketed Fentora beyond its approved indications. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora (“Warning Letter”). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to broaden “the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case.” It further

criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

837. Despite this warning, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq. For example, on January 13, 2012, Cephalon published an insert in Pharmacy Times titled "An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)." Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert states: "It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain."

4. A Guilty Plea and a Large Fine did not Deter Purdue, and its Partner Abbott, from Continuing the Fraudulent Marketing of OxyContin

838. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay nearly \$635 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction, and was unsupported by science. At the time, this was one of the largest settlements with a drug company for marketing misconduct.³⁵⁸ Additionally, Michael Friedman, the company's president, pled guilty to a misbranding charge and agreed to pay \$19 million in fines; Howard R. Udell, Purdue's top lawyer, also pled guilty and agreed to pay \$8 million in fines; and Paul D. Goldenheim, its former medical director, pled guilty as well and agreed to pay \$7.5 million in fines.

839. Nevertheless, even after the settlement, Purdue continued to pay doctors on

³⁵⁸ Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, N.Y. TIMES (May 10, 2007), <http://www.nytimes.com/2007/05/10/business/11drug-web.html>.

speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and to fund seemingly neutral organizations to disseminate the message that opioids were non-addictive as well as other misrepresentations. At least until early 2018, Purdue continued deceptively marketing the benefits of opioids for chronic pain while diminishing the associated dangers of addiction. After Purdue made its guilty plea in 2007, it assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly \$900 million dollars on lobbying and political contributions - eight times what the gun lobby spent during that period.

840. Since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. Physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills (80 mg OxyContin pills or "80s," as they were known on the street, were a prime target for diversion). Purdue claims that health care providers added to the database no longer were detailed, and that sales representatives received no compensation tied to these providers' prescriptions.

841. Yet, Purdue failed to cut off these providers' opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. Purdue's former senior compliance officer acknowledged in an interview with the Los Angeles Times that in five years of investigating suspicious pharmacies, the company never stopped the supply of its opioids to a pharmacy, even where Purdue employees personally witnessed the diversion of its drugs.

842. The same was true of prescribers. For example, as discussed above, despite Purdue's knowledge of illicit prescribing from one Los Angeles clinic which its district manager

called an “organized drug ring” in 2009, Purdue did not report its suspicions until long after law enforcement shut it down and not until the ring prescribed more than 1.1 million OxyContin tablets.

843. Indeed, the New York Attorney General found that Purdue placed 103 New York health care providers on its “No-Call” List between January 1, 2008 and March 7, 2015, and that Purdue’s sales representatives had detailed approximately two-thirds of these providers, some quite extensively, making more than a total of 1,800 sales calls to their offices over a six-year period.

5. Endo Continued to Aggressively Promote Opana After Becoming Aware of Its Widespread Abuse

844. The New York Attorney General found that Endo knew, as early as 2011, that Opana ER was being abused in New York, but certain sales representatives who detailed New York health care providers testified that they did not know about any policy or duty to report problematic conduct. The New York Attorney General further determined that Endo detailed health care providers who were subsequently arrested or convicted for illegal prescribing of opioids a total of 326 times, and these prescribers collectively wrote 1,370 prescriptions for Opana ER (although the subsequent criminal charges at issue did not involve Opana ER).

845. Even after the Indiana Department of Public Health determined that an HIV outbreak in Southeastern Indiana was linked to injection of the prescription painkiller Opana and requested removal from the market, in 2015, “based on its concern that the benefits of the drug may no longer outweigh its risks,” Endo continued to market the drug until 2017.

6. Repeated Admonishments and Fines Did Not Stop the Distributor Defendants from Ignoring Their Obligations to Control the Supply Chain and Prevent Diversion

846. Defendants were repeatedly admonished and even fined by regulatory authorities, but continued to disregard their obligations to control the supply chain of dangerous opioids and to institute controls to prevent diversion.

847. In a *60 Minutes* interview last fall, former DEA agent Joe Rannazzisi described Defendants' industry as "out of control," stating that "[w]hat they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die." The interview continued:

JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.

[INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.

JOE RANNAZZISI: That's not an implication, that's a fact. That's exactly what they did.

848. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing." He explained that "I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."³⁵⁹

849. Government actions against the Distributor Defendants with respect to their obligations to control the supply chain and prevent diversion include:

- a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled

³⁵⁹ *Id.*

- substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Auburn, Washington Distribution Center (“Auburn Facility”) for failure to maintain effective controls against diversion of hydrocodone;
 - c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of hydrocodone;
 - d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Swedesboro, New Jersey Distribution Center (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone;
 - e. On January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;
 - f. On September 30, 2008, Cardinal entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia (“McDonough Facility”), Valencia, California (“Valencia Facility”) and Denver, Colorado (“Denver Facility”);
 - g. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal’s Lakeland Facility for failure to maintain effective controls against diversion of oxycodone; and
 - h. On December 23, 2016, Cardinal agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland Facility.

X. **FACTS PERTAINING TO CLAIMS UNDER RICO STATUTES**

A. **The False Narrative Enterprise**

1. The Common Purpose and Scheme of the False Narrative Enterprise

850. In order to unlawfully increase the demand for opioids, the Marketing Defendants and the Distributor Defendants (the Marketing Defendants, excluding Insys, and the Distributor Defendants are at times collectively referred to as the “RICO-1 Defendants”) formed an association-in-fact enterprise (the “False Narrative Enterprise”) with the Front Groups and KOLs described above. Knowing that their products were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain, the RICO-1 Defendants formed an association-in-fact enterprise and engaged in a scheme to unlawfully increase their profits and sales, and grow their share of the prescription painkiller market, through (1) repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain, and (2) ongoing disregard of their duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market.

2. The Conduct of the False Narrative Enterprise

a. Conduct in the Marketing of Opioids

851. The Marketing Defendants’ substantial financial contribution to the False Narrative Enterprise, and the advancement of opioids- friendly messaging, fueled the U.S. opioids epidemic.³⁶⁰

852. The Marketing Defendants, through their participation in the False Narrative Enterprise, concealed the true risks and dangers of opioids from the medical community and the public, including Plaintiffs, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. The misleading

³⁶⁰ *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members’ Office, (Feb. 12, 2018), <https://www.hsgac.senate.gov/imo/media/doc/reports/Fueling%20an%20Epidemic.pdf> (“Fueling an Epidemic”), at 1.

statements included: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition the Marketing Defendants named “pseudoaddiction;” (4) that withdrawal is easily managed; (5) that increased dosing present no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

853. The Marketing Defendants, the Front Groups, and the KOLs acted together for a common purpose and perpetuated the False Narrative Enterprise’s scheme, including through the unbranded promotion and marketing network as described above.

854. There was regular communication between the Marketing Defendants, Front Groups and KOLs, in which information was shared, misrepresentations are coordinated, and payments were exchanged. Typically, the coordination, communication and payment occurred, and continues to occur, through the repeated and continuing use of the wires and mail in which the Marketing Defendants, Front Groups, and KOLs share information regarding overcoming objections and resistance to the use of opioids for chronic pain. The Marketing Defendants, Front Groups and KOLs functioned as a continuing unit for the purpose of implementing the False Narrative Enterprise’s scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence.

855. At all relevant times, the Front Groups were aware of the Marketing Defendants’ conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same

scheme, to the detriment of consumers, prescribers, and the Plaintiffs. But for the False Narrative Enterprise's unlawful fraud, the Front Groups would have had incentive to disclose the deceit by the Marketing Defendants and the False Narrative Enterprise to their members and constituents. By failing to disclose this information, Front Groups perpetuated the False Narrative Enterprise's scheme and common purpose, and reaped substantial benefits.

856. At all relevant times, the KOLs were aware of the Marketing Defendants' conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct. The Marketing Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. The Marketing Defendants' support helped the KOLs become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the benefits of using opioids to treat chronic pain, repaying the Marketing Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLS and Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and the Plaintiffs. But for the False Narrative Enterprise's unlawful conduct, the KOLs would have had incentive to disclose the deceit by the Marketing Defendants and the False Narrative Enterprise, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs furthered the False Narrative Enterprise's scheme and common purpose, and reaped substantial benefits.

857. As public scrutiny and media coverage focused on how opioids ravaged communities in the relevant RICO states and throughout the United States, the Front Groups and KOLS did not challenge the Marketing Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the False Narrative Enterprise, nor disclose

publicly that the risks of using opioids for chronic pain outweighed their benefits and were not supported by medically acceptable evidence.

858. The Marketing Defendants, Front Groups and KOLs engaged in certain discrete categories of activities in furtherance of the common purpose of the False Narrative Enterprise. As described herein, the False Narrative Enterprise's conduct in furtherance of the common purpose of the False Narrative Enterprise involved: (1) misrepresentations regarding the risk of addiction and safe use of prescription opioids for long-term chronic pain (described in detail above); (2) lobbying to defeat measures to restrict over-prescription; (3) efforts to criticize or undermine CDC guidelines; and (4) efforts to limit prescriber accountability.

859. In addition to disseminating misrepresentations about the risks and benefits of opioids, the False Narrative Enterprise also furthered its common purpose by criticizing or undermining CDC guidelines. Members of the False Narrative Enterprise criticized or undermined the CDC Guidelines which represented “an important step - and perhaps the first major step from the federal government - toward limiting opioid prescriptions for chronic pain.”

860. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized the draft guidelines in 2015, arguing that the “CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest of the individuals who participated in the construction of these guidelines.”

861. The AAPM criticized the prescribing guidelines in 2016, through its immediate past president, stating “that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence.”

862. The Marketing Defendants alone could not have accomplished the purpose of the False Narrative Enterprise without the assistance of the Front Groups and KOLs, who were

perceived as “neutral” and more “scientific” than the Marketing Defendants themselves. Without the work of the Front Groups and KOLs in spreading misrepresentations about opioids, the False Narrative Enterprise could not have achieved its common purpose.

863. The impact of the False Narrative Enterprise’s scheme is still in place - i.e., the opioids continue to be prescribed and used for chronic pain, and the epidemic continues to injure Plaintiffs and consume Plaintiffs’ resources.

864. As a result, it is clear that the Marketing Defendants, the Front Groups, and the KOLs were all willing participants in the False Narrative Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise’s purpose.

865. Each of the Marketing Defendants exerted control over the False Narrative Enterprise and participated in the operation or management of the affairs of the False Narrative Enterprise, directly or indirectly, in the following ways:

- a. Creating and providing a body of deceptive, misleading and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- b. Creating and providing a body of deceptive, misleading and unsupported electronic and print advertisements about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- c. Creating and providing a body of deceptive, misleading and unsupported sales and promotional training materials about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- d. Creating and providing a body of deceptive, misleading and unsupported CMEs and speaker presentations about opioids that (i) understated the risks and

- overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- e. Selecting, cultivating, promoting and paying KOLs based solely on their willingness to communicate and distribute the Marketing Defendants' messages about the use of opioids for chronic pain;
 - f. Providing substantial opportunities for KOLs to participate in research studies on topics the RICO Marketing Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;
 - g. Paying KOLs to serve as consultants or on the Marketing Defendants' advisory boards, on the advisory boards and in leadership positions on Front Groups, and to give talks or present CMEs, typically over meals or at conferences;
 - h. Selecting, cultivating, promoting, creating and paying Front Groups based solely on their willingness to communicate and distribute the RICO Marketing Defendants' messages about the use of opioids for chronic pain;
 - i. Providing substantial opportunities for Front Groups to participate in and/or publish research studies on topics the RICO Marketing Defendants suggested or chose (and paid for), with the predictable effect of ensuring that many favorable studies appeared in the academic literature;
 - j. Paying significant amounts of money to the leaders and individuals associated with Front Groups;
 - k. Donating to Front Groups to support talks or CMEs, that were typically presented over meals or at conferences;
 - l. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;
 - m. Sponsoring CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;
 - n. Developing and disseminating pro-opioid treatment guidelines with the help of the KOLs as authors and promoters, and the help of the Front Groups as publishers, and supporters;
 - o. Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by the RICO Marketing Defendants, such as the elderly, and then funding that distribution;

- p. Concealing their relationship to and control of Front Groups and KOLs from the Plaintiffs and the public at large; and
- q. Intending that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

866. The False Narrative Enterprise had a hierarchical decision-making structure that was headed by the Marketing Defendants and Distributor Defendants, and corroborated by the KOLs and Front Groups. The Marketing Defendants controlled representations made about their opioids and their drugs, doled out funds to PBMs and payments to KOLs, and ensured that representations made by KOLs, Front Groups, and the Marketing Defendants' sales detailers were consistent with the Marketing Defendants' messaging throughout the United States including the relevant RICO states. The Front Groups and KOLs in the False Narrative Enterprise were dependent on the Marketing Defendants for their financial structure and for career development and promotion opportunities.

867. The Front Groups also conducted and participated in the conduct of the False Narrative Enterprise, directly or indirectly, in the following ways:

- a. The Front Groups promised to, and did, make representations regarding opioids and the Marketing Defendants' drugs that were consistent with the Marketing Defendants' messages;
- b. The Front Groups distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;
- c. The Front Groups echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the Marketing Defendants;
- d. The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

- e. The Front Groups strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and
- f. The Front Groups concealed their connections to the KOLs and the Marketing Defendants.

868. The Marketing Defendants' Front Groups, "with their large numbers and credibility with policymakers and the public—have 'extensive influence in specific disease areas.'" The larger Front Groups "likely have a substantial effect on policies relevant to their industry sponsors." "By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic."

869. The KOLs also participated in the conduct of the affairs of the False Narrative Enterprise, directly or indirectly, in the following ways:

- a. The KOLs promised to, and did, make representations regarding opioids and the RICO Marketing Defendants' drugs that were consistent with the Marketing Defendants' messages themselves;
- b. The KOLs distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;
- c. The KOLs echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;
- d. The KOLs issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;
- e. The KOLs strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and
- f. The KOLs concealed their connections to the Front Groups and the RICO Marketing Defendants, and their sponsorship by the Marketing Defendants.

870. The scheme devised and implemented by the Marketing Defendants and members of the False Narrative Enterprise, amounted to a common course of conduct intended to increase the Marketing Defendants' sales from prescription opioids by encouraging the prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

871. As discussed in detail above, the Marketing Defendants funded and controlled the various Front Groups, including APF, AAPM/APS, FSMB, Alliance for Patient Access, USPF, AGS and ACPA. The Front Groups, which appeared to be independent, but were not, transmitted the Marketing Defendants' misrepresentations. The Marketing Defendants and the Front Groups thus worked together to promote the goals of the False Narrative Enterprise.

872. The Marketing Defendants worked together with each other through the Front Groups that they jointly funded and through which they collaborated on the joint promotional materials described above.

873. Similarly, as discussed in detail above, the Marketing Defendants paid KOLs, including Drs. Portenoy, Fine, Fishman, and Webster, to spread their misrepresentations and promote their products. The Marketing Defendants and the KOLs thus worked together to promote the goals of the False Narrative Enterprise.

874. To achieve the common goal and purpose of the False Narrative Enterprise, the Marketing Defendants and members of the False Narrative Enterprise hid from the consumers, prescribers, regulators and the Plaintiffs: (a) the fraudulent nature of the Marketing Defendants' marketing scheme; (b) the fraudulent nature of statements made by the Marketing Defendants and by their KOLs, Front Groups and other third parties regarding the safety and efficacy of

prescription opioids; and (c) the true nature of the relationship between the members of the False Narrative Enterprise.

875. The Marketing Defendants, and each member of the False Narrative Enterprise agreed, with knowledge and intent, to the overall objective of the Marketing Defendants' fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in marketing prescription opioids.

876. Indeed, for the Marketing Defendants' fraudulent scheme to work, each of them had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This conclusion is supported by the fact that the Marketing Defendants each financed, supported, and worked through the same KOLs and Front Groups, and often collaborated on and mutually supported the same publications, CMEs, presentations, and prescription guidelines

877. The Marketing Defendants' predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiffs' business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Marketing Defendants. The predicate acts were committed or caused to be committed by the RICO Marketing Defendants through their participation in the False Narrative Enterprise and in furtherance of its fraudulent scheme.

b. Conduct in the Distribution of Opioids

878. Faced with the reality that they will now be held accountable for the consequences of the opioid epidemic they created, members of the industry resort have categorically denied any criminal behavior or intent. But the RICO-1 Defendants' actions went far beyond what could be considered ordinary business conduct. For more than a decade, the RICO-1 Defendants worked together in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict.

879. As “registrants” under the law of relevant RICO states, the RICO-1 Defendants are duty bound to identify and report “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” Critically, the RICO-1 Defendants’ responsibilities do not end with the products they manufacture or distribute -- there is no such limitation in the law because their duties cut across company lines. Thus, when the RICO-1 Defendants obtain information about the sales and distribution of other companies’ opioid products, as they did through data mining companies like IMS Health, they were legally obligated to report that activity.

880. If morality and the law did not suffice, competition dictates that the Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed, if a manufacturer or distributor could gain market share by reporting a competitor’s illegal behavior (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct dictates that it would do so. Under federal and state RICO statutes this whistleblower or watchdog function is not only a protected choice, but a statutory mandate. Unfortunately, however, that is not what happened. Instead, knowing that investigations into potential diversion would only lead to shrinking markets, the RICO-1 Defendants elected to operate in a conspiracy of silence, in violation of both federal and state law concerning controlled substances, federal RICO, and state RICO laws.

881. The RICO-1 Defendants’ scheme required the participation of all. If any one-member broke rank, its compliance activities would highlight deficiencies of the others, and their scheme would crumble. But, if all the members of the enterprise conducted themselves in the same manner, it would be difficult for the government authorities to go after any one of them. Accordingly, through the connections they made as a result of their participation in the Healthcare

Distribution Alliance (“HDA”), the Defendants chose to flout the closed system designed to protect the citizens. Publicly, in 2008, they announced their formulation of “Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances.” But, privately, Defendants refused to act and through their lobbying efforts, they collectively sought to undermine the impact of government regulation and enforcement. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize these Defendants’ duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is “difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications.” Yet, the RICO-1 Defendants apparently all found the same profit-maximizing balance - intentionally remaining silent to ensure the largest possible financial return.

882. As described above, at all relevant times, the RICO-1 Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits. In support of this common purpose and fraudulent scheme, the RICO-1 Defendants jointly agreed to disregard their duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market.

883. At all relevant times, as described above, the RICO-1 Defendants exerted control over, conducted and/or participated in the False Narrative Enterprise by fraudulently claiming that they were complying with their duties to maintain effective controls against diversion, including duties to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, and to halt such unlawful sales, so as to generate unlawful profits.

884. The RICO-1 Defendants disseminated false and misleading statements to state and federal regulators claiming that:

- a. they were complying with their obligations to maintain effective controls against diversion of their prescription opioids;
- b. they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids;
- c. they were complying with their obligation to report suspicious orders or diversion of their prescription opioids; and
- d. they did not have the capability to identify suspicious orders of controlled substances.

885. The RICO-1 Defendants applied political and other pressure to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied for less stringent regulation of their marketing and distribution of pharmaceutical products.

886. The RICO-1 Defendants are required to make reports of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

887. The RICO-1 Defendants knowingly and intentionally furnished false or fraudulent information in their reports about suspicious orders, and/or omitted material information from reports, records and other documents required to be filed. Specifically, the RICO-1 Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to take responsive action. This failure included the failure to report this information to the government.

888. The RICO-1 Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal

of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

889. In devising and executing the illegal scheme, the RICO-1 Defendants devised and knowingly carried out a scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

890. For the purpose of executing the illegal scheme, the RICO-1 Defendants committed unlawful acts, which number in the thousands, intentionally and knowingly, with the specific intent to advance the illegal scheme. These unlawful acts, which included repeated acts of mail fraud and wire fraud, constituted a pattern of unlawful activity.

891. The RICO-1 Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce.

892. Each of the Defendants identified manufactured, shipped, paid for and received payment for the drugs identified above, throughout the United States.

893. The RICO-1 Defendants used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO-1 Defendants made misrepresentations about their compliance with the statutes, regulations and other laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

894. At the same time, the RICO-1 Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with federal and state laws

regarding the identification and reporting of suspicious orders of prescription opioids. The RICO-1 Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

895. The RICO-1 Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail with each other and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

896. The mail and wire transmissions described herein were made in furtherance of the RICO-1 Defendants' scheme and common course of conduct to deceive regulators, the public and the Plaintiffs that these RICO-1 Defendants were complying with their legal obligations to identify and report suspicious orders of prescription opioids all while RICO-1 Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market.

897. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden by the RICO-1 Defendants and cannot be alleged without access to the RICO-1 Defendants' books and records. However, Plaintiffs have described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

898. The RICO-1 Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with these RICO-1 Defendants in these offenses

and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the Defendants.

899. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

900. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiffs' business and property, while simultaneously generating billion-dollar revenue and profits for the RICO-1 Defendants. The predicate acts were committed or caused to be committed by the RICO-1 Defendants through their participation in the False Narrative Enterprise and in furtherance of its fraudulent scheme.

901. As described above, the RICO-1 Defendants were repeatedly warned, fined, and found to be in violation of applicable law and regulations, and yet they persisted. The sheer volume of enforcement actions against the RICO-1 Defendants supports this conclusion that the RICO-1 Defendants operated through a pattern and practice of willfully and intentionally omitting information from their mandatory reports.

902. Each instance of unlawful activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims. The RICO-1 Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this State, its citizens or the Plaintiffs. The RICO-1 Defendants were aware that Plaintiffs and others rely on these RICO-1 Defendants to maintain a

closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

903. By intentionally refusing to report and halt suspicious orders of their prescription opioids, the Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of unlawful activity.

3. Pattern of Unlawful Activity

904. The RICO-1 Defendants' scheme described herein was perpetrated, in part, through multiple acts of mail fraud and wire fraud, and violations of statutes regulating the distribution of controlled substances, constituting a pattern of unlawful activity as described herein.

905. The pattern of unlawful activity used by the False Narrative Enterprise likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful False Narrative Enterprise.

906. These communications included essentially uniform misrepresentations, concealments and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute and non-cancer pain, with the goal of profiting from increased sales of the Marketing Defendants' drugs induced by consumers, prescribers, regulators and Plaintiffs' reliance on the Marketing Defendants' misrepresentations. Each of these fraudulent mailings and interstate wire transmissions constitutes unlawful acts and collectively, these violations constitute a pattern of unlawful activity, through which the Marketing Defendants, the Front Groups and the KOLs defrauded and intended to defraud Plaintiffs. The Marketing Defendants devised and knowingly carried out an illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the safe, non-addictive and effective use of opioids for long-term chronic, non-acute and non-cancer pain. The Marketing Defendants and members of the False Narrative Enterprise knew

that these representations violated the FDA approved use these drugs, and were not supported by actual evidence. The Marketing Defendants intended that that their common purpose and scheme to defraud would, and did, use the U.S. Mail and interstate wire facilities, intentionally and knowingly with the specific intent to advance, and for the purpose of executing, their illegal scheme. By intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for chronic pain, to, prescribers, regulators and the public, including Plaintiffs, the Marketing Defendants, the Front Groups and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of unlawful activity. The Marketing Defendants' use of the U.S. Mail and interstate wire facilities to perpetrate the opioids marketing scheme involved thousands of communications, publications, representations, statements, electronic transmissions, payments, including, inter alia:

- a. Marketing materials about opioids, and their risks and benefits, which the RICO Marketing Defendants sent to health care providers, such as hospitals transmitted through the internet and television, published, and transmitted to Front Groups and KOLs located across the country and the State;
- b. Written representations and telephone calls between the RICO Marketing Defendants and Front Groups regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;
- c. Written representations and telephone calls between the RICO Marketing Defendants and KOLs regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;
- d. E-mails, telephone and written communications between the RICO Marketing Defendants and the Front Groups agreeing to or implementing the opioids marketing scheme;
- e. E-mails, telephone and written communications between the RICO Marketing Defendants and the KOLs agreeing to or implementing the opioids marketing scheme;

- f. Communications between the RICO Marketing Defendants, Front Groups and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the False Narrative Enterprise;
- g. Communications between the RICO Marketing Defendants, KOLs and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the False Narrative Enterprise;
- h. Written and oral communications directed to State agencies, federal and state courts, and private insurers throughout the State that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and
- i. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities - the wrongful proceeds of the scheme.

In addition to the above-referenced predicate acts, it was intended by and foreseeable to the Marketing Defendants that the Front Groups and the KOLs would distribute publications through the U.S. Mail and by interstate wire facilities, and, in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.

907. The RICO-1 Defendants' use of U.S. Mail and interstate wires in conduct related to the distribution of opioids includes, but is not limited to, the transmission, delivery, or shipment of the following by the RICO-1 Defendants, and/or third parties that were foreseeably caused to be sent as a result of the RICO-1 Defendants' illegal scheme, of the following:

- a. The prescription opioids themselves;
- b. Documents and communications that facilitated the manufacture, purchase and sale of prescription opioids;
- c. RICO-1 Defendants' government registrations;
- d. Documents and communications that supported and/or facilitated RICO-1 Defendants' government registrations;
- e. RICO-1 Defendants' records and reports that were required to be submitted to regulatory authorities;

- f. Documents intended to facilitate the manufacture and distribution of the RICO-1 Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;
- g. Documents for processing and receiving payment for prescription opioids;
- h. Payments from the Distributors to the Marketing Defendants;
- i. Rebates and chargebacks from the Marketing Defendants to the Distributors Defendants;
- j. Payments to the RICO-1 Defendants' lobbyists through the PCF;
- k. Payments to the RICO-1 Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;
- l. Deposits of proceeds from the RICO-1 Defendants' manufacture and distribution of prescription opioids; and
- m. Other documents and things, including electronic communications.

908. The RICO-1 Defendants also participated in a pattern of violations of the federal Controlled Substances Act and analogous state common and statutory law by refusing to comply with their obligations under the law to report suspicious orders and prescribers.

B. The Sackler Pharmaceutical Enterprise

1. The Common Purpose and Scheme of the Sackler Pharmaceutical Enterprise

909. In order to unlawfully increase the demand for opioids, the Purdue Defendants formed an association-in-fact enterprise (the "Sackler Pharma Enterprise," commonly referred to colloquially, but not referred to here, as "Purdue") that also included other affiliated business entities beneficially owned by the Sackler Defendants, and employees of Purdue, not named as Defendants. The Sackler Pharma Enterprise was a single family-owned criminal enterprise that operated through and across many business entities. Knowing that their products were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain, the Sackler Pharma Enterprise, owned, directed and controlled at all times by the

Sackler Defendants, engaged in a scheme to unlawfully increase their profits and sales, and grow their share of the prescription painkiller market, through (1) repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain, and (2) ongoing disregard of their duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market.

2. The Conduct of the Sackler Pharmaceutical Enterprise

910. The Purdue Defendants regularly directed their agents, including a veritable army of sales representatives, to make, and at times themselves made, statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. The misleading statements included: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition the Marketing Defendants named “pseudoaddiction;” (4) that withdrawal is easily managed; (5) that increased dosing present no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse. Misleading statements were also disseminated by the Sackler Pharma Enterprise (1) through the use of front groups, KOLs and/or other ostensible medical experts, who were paid by the Sackler Pharma Enterprise (directly through fees, and also through grants and donations to favored institutions) to amplify these false and misleading statements, and (2) through the use of lobbyists who directly lobbied state and federal legislators to take positions favorable to the Sackler Pharma Enterprise and the RICO-1 Defendants. Each of the Purdue Defendants participated in the operation or management of the affairs of the Sackler Pharma Enterprise, directly or indirectly, in the following ways:

- a. Creating and providing a body of deceptive, misleading and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- b. Creating and providing a body of deceptive, misleading and unsupported electronic and print advertisements about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- c. Creating and providing a body of deceptive, misleading and unsupported sales and promotional training materials about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- d. Creating and providing a body of deceptive, misleading and unsupported CMEs and speaker presentations about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- e. Selecting, cultivating, promoting and paying KOLs based solely on their willingness to communicate and distribute the Purdue Defendants' messages about the use of opioids for chronic pain;
- f. Providing substantial opportunities for KOLs to participate in research studies on topics the Purdue Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;
- g. Paying KOLs to serve as consultants or on the advisory boards and in leadership positions on Front Groups, and to give talks or present CMEs, typically over meals or at conferences;
- h. Selecting, cultivating, promoting, creating and paying Front Groups based solely on their willingness to communicate and distribute the Purdue Defendants' messages about the use of opioids for chronic pain;
- i. Providing substantial opportunities for Front Groups to participate in and/or publish research studies on topics the Purdue Defendants suggested or chose (and paid for), with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

- j. Paying significant amounts of money to the leaders and individuals associated with Front Groups;
- k. Donating to Front Groups to support talks or CMEs, that were typically presented over meals or at conferences;
- l. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;
- m. Sponsoring CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;
- n. Developing and disseminating pro-opioid treatment guidelines with the help of the KOLs as authors and promoters, and the help of the Front Groups as publishers, and supporters;
- o. Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by the Purdue Defendants, such as the elderly, and then funding that distribution;
- p. Concealing their relationship to and control of Front Groups and KOLs from the Plaintiffs and the public at large; and
- q. Intending that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

911. As a “registrant” under federal and state law, Purdue is bound to identify and report “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” Critically, these responsibilities do not end with the products it manufactures or distributes -- there is no such limitation in the law because their duties cut across company lines. The Purdue Defendants, including the Sackler Defendants, and their employees, were well aware of the identity of suspicious prescribers and supply channels through whom there was a significant probability of unethical/illegal prescribing and/or product diversion. The Purdue Defendants regularly received (1) hotline calls, (2) “Reports of Concern” and (3) other reports of adverse events, of which all of the Purdue Defendants were aware. The stunning volume of these incidents

was regularly discussed, from the sales representatives to the Board level, and was known throughout the Sackler Pharma Enterprise. The Purdue Defendants agreed to remain silent about compromised practitioners and supply channels that were well known to them, instead of reporting them to federal and state authorities as they were required to do. The Sackler Pharma Enterprise also disseminated false and misleading statements to state and federal regulators claiming that:

- a. they were complying with their obligations to maintain effective controls against diversion of their prescription opioids;
- b. they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids;
- c. they were complying with their obligation to report suspicious orders or diversion of their prescription opioids; and
- d. they did not have the capability to identify suspicious orders of controlled substances.

912. The Purdue Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme.

913. There was regular communication among the Purdue Defendants, in which information was shared, misrepresentations are coordinated, and payments were exchanged. Typically, the coordination, communication and payment occurred, and continues to occur, through the repeated and continuing use of the wires, including the use of electronic mail, and telephone calls both to facilitate board and committee meetings and one-to-one conversations in furtherance of the illegal scheme.

914. There was regular communication between the Purdue Defendants and others, in furtherance of the scheme, through the repeated and continuing use of the wires and U.S. Mail, including the dissemination of false and misleading advertising and marketing materials generated by or at the direction of the Purdue Defendants, and the transmission of false and misleading

information concerning Purdue's purported compliance with its reporting obligations and other obligations under federal and state law.

3. Pattern of Unlawful Activity

915. The Purdue Defendants' scheme described herein was perpetrated, in part, through multiple acts of mail fraud and wire fraud, and violations of statutes regulating the distribution of controlled substances, constituting a pattern of unlawful activity as described herein.

916. The pattern of unlawful activity used by the Sackler Pharma Enterprise likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Sackler Pharma Enterprise.

917. These communications included essentially uniform misrepresentations, concealments and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute and non-cancer pain, with the goal of profiting from increased sales of the Purdue's drugs induced by consumers, prescribers, regulators and Plaintiffs' reliance on the Purdue's misrepresentations. Each of these fraudulent mailings and interstate wire transmissions constitutes unlawful acts and collectively, these violations constitute a pattern of unlawful activity, through which the Purdue Defendants defrauded and intended to defraud Plaintiffs and others. The Marketing Defendants devised and knowingly carried out an illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the safe, non-addictive and effective use of opioids for long-term chronic, non-acute and non-cancer pain. The Marketing Defendants and members of the False Narrative Enterprise knew that these representations violated the FDA approved use of these drugs, and were not supported by actual evidence. The Marketing Defendants intended that their common purpose and scheme to defraud would, and did, use the U.S. Mail and interstate wire facilities, intentionally and knowingly with the specific intent to

advance, and for the purpose of executing, their illegal scheme. By intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for chronic pain, to, prescribers, regulators and the public, including Plaintiffs, the Marketing Defendants, the Front Groups and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of unlawful activity. The Purdue Defendants' use of the U.S. Mail and interstate wire facilities to perpetrate their opioids marketing scheme involved thousands of communications, publications, representations, statements, electronic transmissions, payments, including, inter alia:

- a. Marketing materials about opioids, and their risks and benefits, which the Purdue Defendants sent to health care providers, such as hospitals transmitted through the internet and television, published, and transmitted to Front Groups and KOLs located across the country and the State;
- b. Written representations and telephone calls between the Purdue Defendants and Front Groups regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;
- c. Written representations and telephone calls between the Purdue Defendants and KOLs regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;
- d. E-mails, telephone and written communications between the Purdue Defendants and the Front Groups agreeing to or implementing the opioids marketing scheme;
- e. E-mails, telephone and written communications between the Purdue Defendants and the KOLs agreeing to or implementing the opioids marketing scheme;
- f. Communications between the Purdue Defendants, Front Groups and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the False Narrative Enterprise;
- g. Communications between the Purdue Defendants, KOLs and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the False Narrative Enterprise;

- h. Written and oral communications directed to State agencies, federal and state courts, and private insurers throughout the State that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and
- i. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities - the wrongful proceeds of the scheme.

In addition to the above-referenced predicate acts, it was intended by and foreseeable that other persons, including the Front Groups and the KOLs, would distribute publications through the U.S. Mail and by interstate wire facilities, and, in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.

918. The Purdue Defendants' use of U.S. Mail and interstate wires in conduct related to the distribution of opioids includes, but is not limited to, the transmission, delivery, or shipment of the following by the Purdue Defendants, and/or third parties that were foreseeably caused to be sent as a result of Purdue's illegal scheme, of the following:

- a. The prescription opioids themselves;
- b. Documents and communications that facilitated the manufacture, purchase and sale of prescription opioids;
- c. Purdue's government registrations;
- d. Documents and communications that supported and/or facilitated Purdue's government registrations;
- e. Purdue's records and reports that were required to be submitted to regulatory authorities;
- f. Documents intended to facilitate the manufacture and distribution of the Purdue's prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;
- g. Documents for processing and receiving payment for prescription opioids;
- h. Payments from the Distributors to the Marketing Defendants;
- i. Rebates and chargebacks from the Marketing Defendants to the Distributors Defendants;

- j. Payments to Purdue's lobbyists through the PCF;
- k. Payments to Purdue's trade organizations, like the HDA, for memberships and/or sponsorships;
- l. Deposits of proceeds from Purdue's manufacture and distribution of prescription opioids; and
- m. Other documents and things, including electronic communications.

919. The Purdue Defendants also participated in a pattern of violations of the federal Controlled Substances Act and analogous state common and statutory law by refusing to comply with their obligations under the law to report suspicious orders and prescribers.

XI. TOLLING AND FRAUDULENT CONCEALMENT

920. Defendants, individually and acting through their employees and agents, knowingly and intentionally concealed material facts and knowledge from Plaintiffs and others to induce them to purchase and administer opioids as set forth in detail above.

921. The Defendants invented the term "pseudoaddiction" and promoted it to the medical community, including Plaintiffs. Defendants provided the medical community, including Plaintiffs, with false and misleading information about ineffectual medical strategies to avoid or control opioid addiction. Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales.

922. In overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addition and death; in falsely promoting abuse-deterring formulations as reducing abuse; in falsely claiming that OxyContin provides 12 hours of relief; in falsely portraying their efforts or commitment to rein in the supply

and diversion of opioids; and doing all of this while knowing full well that their statements were misrepresentations of facts material, Defendants have engaged in intentional, fraudulent misrepresentations and concealment of the material fact, as detailed herein.

923. Defendants intended that Plaintiffs would rely on their misrepresentations, omissions, and concealment, knew that Plaintiffs would rely on their misrepresentations, and that such reliance would cause harm to Plaintiffs. The medical community, including Plaintiffs, were duped by the Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing.

924. Plaintiffs reasonably relied on Defendants' misrepresentations and omissions in writing and filling prescriptions for Defendants' opioids. The use of Defendants' opioid medicines became widespread and continuous as a result.

925. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The harm is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants have not ceased. The nuisance created by Defendants remains unabated.

926. Plaintiffs' claims are equitably tolled because Defendants knowingly and fraudulently concealed the facts and their wrongful acts, and the material information pertinent to their discovery, which Defendants concealed them from the Plaintiffs. Plaintiffs did not know, or could not have known through the exercise of reasonable diligence, of its claims, as a result of Defendants' conduct.

927. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew or could have known about

Defendants' unlawful actions because Defendants made deliberate efforts to conceal their conduct. As a result of the above, Plaintiffs were unable to obtain vital information bearing on its claims absent any fault or lack of diligence on their part.

928. Plaintiffs seek economic losses (direct, incidental, or consequential pecuniary losses) resulting from the negligence of Defendants. They do not seek damages which may have been suffered by individual citizens for wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by the actions of Defendants.

929. Plaintiffs suffered actual pecuniary damages proximately caused by Defendants concealment of material fact, which include but are not limited to, expending funds on emergency services, emergency response, additional training, additional security, and other services Plaintiffs would not have incurred.

930. Plaintiffs have incurred expenditures for special programs over and above their ordinary hospital services.

931. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a hospital would reasonably expect to occur and is not part of the normal and expected costs of a hospital's existence. Plaintiffs allege wrongful acts which were neither discrete nor of the sort a hospital can reasonably expect.

XII. CLASS ACTION ALLEGATIONS

932. This action is brought as a plaintiffs' class action pursuant to Federal Rule of Civil Procedure 23(b)(3). Plaintiffs bring this action on their own behalf, and on behalf of all others similarly situated, as representatives of the following Class:

All hospitals in the United States which treated patients with opioid conditions "Patients with opioid conditions" are defined as patients with opioid overdose; patients with opioid addiction; babies born opioid addicted; opioid users committed to mental health treatment

programs; and opioid users with pretextual excuses for obtaining opioids.

Excluded from the Class are any hospitals directly or indirectly owned or operated by Defendants or Defendants' affiliated entities.

933. The members of the Class are readily identifiable from public records.

934. Upon information and belief, the Class consists of thousands of members, and is therefore so numerous that individual joinder of all members is impracticable. The members of the Class are geographically dispersed throughout the United States.

935. There are questions of law and fact common to the Class, which predominate over any questions affecting only individual members of the Class. The wrongs suffered and remedies sought by Plaintiffs and the other members of the Class are premised upon a uniform unlawful scheme perpetuated by Defendants. The sole question affecting only individual members of the Class is the exact monetary recovery to which each Class member is entitled. Plaintiffs' and the Class members' use of uniform billing codes for patients with opioid conditions will render this determination a simple mechanical one. Questions common to the Class include, but are not limited to, the following:

- a. Did the Manufacturer Defendants use false and deceptive statements and omissions to market opioids?
- b. Did the Manufacturer Defendants market opioids by misrepresenting the risks and benefits of opioids?
- c. Did the Manufacturer Defendants and the Distributor Defendants fail to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids?
- d. Did the Defendants fail to monitor, detect, investigate, refuse to fill, and report orders of prescription opioids which they knew or should have known were likely to be diverted for nonmedical purposes?
- e. Did the Defendants conduct the affairs of an enterprise through a pattern of unlawful or otherwise prohibited activity?

- f. Did the Defendants conspire to conduct the affairs of an enterprise through a pattern of unlawful or otherwise prohibited activity?
- g. Did the Manufacturer Defendants negligently manufacture, market, and sell opioids?
- h. Did the Distributor Defendants negligently sell and distribute opioids?
- i. Did the Manufacturer Defendants wantonly, recklessly, or with gross negligence manufacture, market, and sell opioids?
- j. Did the Distributor Defendants wantonly, recklessly, or with gross negligence sell and distribute opioids?
- k. Did the Defendants commit common-law fraud by making false representations of material fact and by concealing material facts about opioids?
- l. Were Plaintiffs and the Class members monetarily damaged as a direct and proximate result of the Defendants' acts and omissions?

936. Plaintiffs' claims are typical of those of the Class, and are based on the same legal theories as those of the Class members. Plaintiffs' claims and those of the Class members all arise from the same pattern or practice by the Defendants, set out above.

937. Plaintiffs will fairly and adequately protect the interests of the members of the Class. Plaintiffs have retained counsel who are highly experienced and competent in complex consumer class-action litigation, and Plaintiffs and their counsel intend to prosecute this action vigorously. Neither Plaintiffs nor their counsel have any interests that might cause them not to vigorously pursue this action. Plaintiffs' interests are coextensive with those of the Class, and Plaintiffs have no interests adverse to those of the Class members.

938. Plaintiffs have made arrangements with their counsel for the discharge of their financial responsibilities to the Class. Plaintiffs' counsel has the necessary financial resources to adequately and vigorously litigate this class action.

939. A class action is superior to all other available means for the fair and efficient adjudication of this controversy. It is desirable to concentrate the litigation of the claims in this forum, because the damages suffered by the individual Class members are relatively small compared to the burden and expense that would be entailed by individual litigation of their claims against Defendants. Moreover, the individual Class members are unlikely to be aware of their rights. Thus, it is unlikely that the Class members, on an individual basis, can obtain effective redress for the wrongs done to them. Additionally, the court system would be adversely affected by such individualized litigation. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase delay and expense to all parties and the court system from the issues raised by this action. In contrast, the class-action device provides the benefit of adjudication of these issues in a single proceeding, with economies of scale and comprehensive supervision by a single court.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Violation Of RICO, 18 U.S.C. § 1961, *et seq.* – Opioid False Narrative Enterprise (Against All Defendants)

940. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

941. This Claim for relief alleges violations of §§ 1962(c) and (d) of RICO, 18 U.S.C. §§ 1962(c) & (d).

942. At all relevant times, Plaintiffs were entities capable of holding a legal or beneficial interest in property, which means that they were “person[s]” within the meaning of Sections 1961(3) and 1962(c) of RICO, 18 U.S.C. §§ 1961(3) & 1962(c).

I. The False Narrative Enterprise

943. **Name, Purposes and Membership.** At all relevant times, there existed an “enterprise,” within the meaning of 18 U.S.C. §§ 1961(4) & 1962(c) – to wit, an association-in-fact comprised of each of the Defendants - The False Narrative Enterprise. The lawful purpose of the False Narrative Enterprise was the manufacture, marketing and sale of pharmaceutical products in interstate and foreign commerce. The unlawful purpose of the False Narrative Enterprise was to engage in and carry out an intentional scheme to defraud purchasers, including doctors and hospitals, by propagating falsehoods about the safety and benefits of opioids.

944. **Continuity:** The continuity of the False Narrative Enterprise was coterminous with the period of time necessary to defraud Plaintiff, other hospitals, physicians, other healthcare providers, patients and their families, and the American public in general.

945. **Effect on Commerce:** The False Narrative Enterprise was engaged in, and its activities affected, interstate and foreign commerce.

946. **Predicate Acts:** At all relevant times, Defendants, in violation of Section 1962(c) of RICO, 18 U.S.C. § 1962(c), conducted (managed) or participated, directly or indirectly, in the conduct (management) of the False Narrative Enterprise, through a pattern of unlawful or otherwise prohibited activity, by engaging in multiple, repeated, and continuous violations of the federal wire fraud statute, 18 U.S.C. § 1343, and the federal mail fraud statute, 18 U.S.C. § 1341, and the Controlled Substances Act, 21 U.S.C. 801, *et seq.* The Defendants transmitted communications through U.S. mail fraud and interstate wire fraud, in interstate or foreign commerce, to designated persons for ostensibly legitimate purposes, but with the actual, unlawful purpose of engaging in an intentional scheme to defraud Plaintiff, other hospitals, health care providers, patients and their families and, in general, the American public.

947. **Structure of the False Narrative Enterprise:** The False Narrative Enterprise reflected several types of participants, not all of which were complicit, and not all of which are named herein as Defendants:

A. **The Marketing Defendants.** The Marketing Defendants are Purdue, Actavis, Cephalon, Janssen, Endo, Insys, Abbott, Amneal Pharmaceuticals, LLC, Depomed, and Mallinckrodt. The Marketing Defendants conceptualized and set in motion the falsehoods about opioids that created billions of dollars of artificial demand for these highly addictive and dangerous products.

B. **The Front Groups.** The Marketing Defendants used the Front Groups, such as the American Pain Foundation, American Academy of Pain Medicine, the American Pain Society, the Federation of State Medical Boards, the Alliance for Patient Access, the U.S. Pain Foundation, the American Geriatrics Society, and the American Chronic Pain Association, not named as defendants herein and not all of which were fully complicit, to stoke demand for opioids by falsely creating the impression of independent third party authoritative validation of the false claims of the Marketing Defendants.

C. **The KOLs.** The Marketing Defendants used KOLs, such as Dr. Portenoy, Dr. Webster, Dr. Fine and Dr. Fishman, not named as defendants herein and who may not have been fully complicit, to provide ostensibly valid, third party, authoritative validation of the false claims of the Marketing Defendants.

D. **The Distributor Defendants.** The Distributor Defendants are Anda, Inc., Cardinal, H.D. Smith, LLC, Henry Schein Entities, Miami-Luken, McKesson Corporation, and AmerisourceBergen; they joined the False Narrative Enterprise with full awareness and complicity, and acted in concert with the Marketing Defendants to pool information about

vulnerable targets and share the king size profits reaped from the sale of opioids to addicts, deliberately ignoring their obligations under the Controlled Substances Act.

E. **Corrupt Physicians and Pharmacies, a/k/a the Pill Mills.** These participants, not named as defendants herein, prescribed opioids illegally and with no basis in legitimate medicine; and dispensed opioids illegally and in direct violation of their legal obligations

F. **The National Retail Pharmacies.** The National Retail Pharmacies are CVS, Kroger, Rite-Aid, Walgreens, and Wal-Mart. Like the Distributor Defendants, they joined the False Narrative Enterprise with full awareness and complicity, and acted in concert with the Marketing Defendants to pool information about vulnerable targets and share the king size profits reaped from the sale of opioids to addicts, deliberately ignoring their obligations under the Controlled Substances Act.

948. In violation of Section 1962(d) of RICO, 18 U.S.C. § 1962(d), the Defendants, with full knowledge and purpose, conspired to violate Section 1962(c) of RICO.

II. Consequences

949. By reason of the above-referenced violations of 18 U.S.C. §§ 1962(c) & (d), Plaintiffs were injured in their business or property within 18 U.S.C. § 1964(c) of RICO, is entitled to assert this claim, and to recover threefold the damages they sustained, as demonstrated at trial, and the cost of the suit, including reasonable attorneys' fees, as well as such other appropriate relief, as the Court may provide.

SECOND CLAIM FOR RELIEF

Violation Of RICO, 18 U.S.C. § 1961, *et seq.* – Sackler Pharma Enterprise (Against Companies and Individuals Associated with Purdue)

950. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

951. This Claim for relief alleges violations of §§ 1962 of RICO, 18 U.S.C. §§ 1962.

952. At all relevant times, Plaintiffs were entities capable of holding a legal or beneficial interest in property, which means that they were “person[s]” within the meaning of Sections 1961(3) and 1962 of RICO, 18 U.S.C. §§ 1961(3) & 1962.

I. The Sackler Pharmaceutical Enterprise

953. **Name, Purposes and Membership.** At all relevant times, there existed an “enterprise,” within the meaning of 18 U.S.C. §§ 1961(4) & 1962 – to wit, an association-in-fact comprised of each of the Purdue Defendants and certain other persons identified below - the Sackler Pharma Enterprise. The lawful purpose of the Sackler Pharma Enterprise was the manufacture, marketing and sale of pharmaceutical products in interstate and foreign commerce. The unlawful purpose of the Sackler Pharma Enterprise was to engage in and carry out an intentional scheme to defraud purchasers, including doctors and hospitals, by propagating falsehoods about the safety and benefits of opioids.

954. **Continuity:** The continuity of the Sackler Pharma Enterprise was coterminous with the period of time necessary to defraud Plaintiffs, other hospitals, physicians, other healthcare providers, patients and their families, and the American public in general.

955. **Effect on Commerce:** The Sackler Pharma Enterprise was engaged in, and its activities affected, interstate and foreign commerce.

956. **Predicate Acts:** At all relevant times, Defendants engaged in multiple, repeated, and continuous violations of the federal wire fraud statute, 18 U.S.C. § 1343, and the federal mail fraud statute, 18 U.S.C. § 1341, and the Controlled Substances Act, 21 U.S.C. 801, *et seq.* Defendants transmitted communications through U.S. mail fraud and interstate wire fraud, in interstate or foreign commerce, to designated persons for ostensibly legitimate purposes, but with the actual, unlawful purpose of engaging in an intentional scheme to defraud Plaintiffs, health care

providers, patients and their families and, in general, the American public. At all relevant times, in violation of Section 1962(a) of RICO, 18 U.S.C. § 1962(a) and through the above-referenced pattern of unlawful or otherwise prohibited activity, Defendants, having income derived, directly or indirectly, from a pattern of unlawful or otherwise prohibited activity, in which it participated as a principal within the meaning of 18 U.S.C. § 1962, used or invested, directly or indirectly, part of such income in itself, an enterprise. At all relevant times, in violation of Section 1962(b) of RICO, 18 U.S.C. § 1962(b), and through the above-referenced pattern of unlawful or otherwise prohibited activity, Defendants acquired or maintained, directly or indirectly, an interest (control) in the Sackler Pharma enterprise that has been engaged in interstate or foreign commerce. At all relevant times, Defendants, in violation of Section 1962(c) of RICO, 18 U.S.C. § 1962(c), conducted (managed) or participated, directly or indirectly, in the conduct (management) of the Sackler Pharma Enterprise, through the above-referenced pattern of unlawful or otherwise prohibited activity. In violation of Section 1962(d) of RICO, 18 U.S.C. § 1962(d), Defendants, with full knowledge and purpose, conspired to violate Section 1962 (a), (b) or (c) of RICO, 18 U.S.C. § 1962(a)-(c).

957. Structure of the Purdue Pharma Enterprise: The Sackler Pharma Enterprise reflected several types of participants, not all of whom were complicit, and not all of which are named herein as Defendants:

A. **The Sackler Defendants.** The Sackler Defendants are Richard Sackler, Beverly Sackler, David Sackler, Ilene Sackler Lefcourt, Jonathan Sackler, Kathe Sackler, Mortimer Sackler, and Theresa Sackler controlled Purdue's misconduct. The Sackler Defendants conceptualized and set in motion the falsehoods about opioids that created billions of dollars of artificial demand

for these highly addictive and dangerous products. Together, the Sackler Defendants directed and otherwise participated in Purdue's deceptive sales and marketing practices, sending hundreds of orders to executives and other employees. From the money that Purdue collected as a result of its wrongful conduct, they paid themselves and their family billions of dollars.

- B. Other Purdue Directors:** The members of the Purdue Board who are not members of the Sackler family, although not named as defendants herein, each joined and participated in the Sackler Pharma Enterprise with full awareness and complicity, acted in concert with the Sackler Defendants to direct Purdue's deception and/or carry out the misconduct and share the king size profits reaped from the sale of opioids to Plaintiffs, health care providers, patients and their families and, in general, the American public.
- C. The Purdue Officer Defendants:** The Purdue Officer Defendants are John Stewart, Mark Timney, Craig Landau and Russell Gasdia. The Purdue Officer Defendants each joined and participated in the Sackler Pharma Enterprise with full awareness and complicity, acted in concert with the Sackler defendants to direct Purdue's deception and/or carry out the misconduct and share the king size profits reaped from the sale of opioids to Plaintiffs, health care providers, patients and their families and, in general, the American public.
- D. The Purdue Entity Defendants and Other Affiliated Entities:** The Purdue Entity Defendants are Purdue Pharma L.P., Purdue Pharma Inc. and The Purdue Frederick Company, Inc. The Purdue Entity Defendants, and other business entities beneficially owned and controlled by the Sackler Defendants

not named as defendants herein, joined the Sackler Pharma Enterprise with full awareness and complicity, and acted in concert with the Sackler Defendants to pool information about vulnerable targets and share the king size profits reaped from the sale of opioids to Plaintiffs, health care providers, patients and their families and, in general, the American public, deliberately ignoring duties to comply with laws and regulations on marketing and sales of controlled substances.

E. The Purdue Sales Representatives and Other Employees: These participants are not named as defendants herein and who may not have been fully complicit. The Purdue Sales Representatives implemented marketing and sales plans under the direction and control of the Sackler Defendants, the Purdue Director and Purdue Officer Defendants, including pooling information about vulnerable targets, increasing sales of highly addictive opioids directly to Plaintiffs and physicians, concealing risks of opioids, as well as sharing the king size profits reaped from the sale of opioids to Plaintiffs, health care providers, patients and their families and, in general, the American public.

II. Consequences

958. By reason of the above-referenced violations of 18 U.S.C. §§ 1962, Plaintiffs were injured in their business or property within 18 U.S.C. § 1964(c) of RICO, are entitled to assert this claim, and to recover threefold the damages they sustained, as demonstrated at trial, and the cost of the suit, including reasonable attorneys' fees, as well as such other appropriate relief, as the Court may provide.

THIRD CLAIM FOR RELIEF

**Negligence
(Against All Defendants)**

959. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

960. This claim is brought under the common law of negligence.

I. The Marketing Defendants and Distributor Defendants Owed a Duty of Care

961. The Marketing Defendants and Distributor Defendants had a duty to exercise reasonable care in the manufacturing, marketing, selling, and distributing of highly dangerous opioid drugs. These Defendants knew or should have known that opioids were unreasonably dangerous and were likely to cause addiction and death. These Defendants owed its aforesaid duties to Plaintiffs because the injuries alleged herein were direct and foreseeable by the Marketing and Distributor Defendants.

962. A reasonable person could foresee the probability of occurrence of injury to Plaintiffs. Reasonably prudent wholesale drug manufactures, marketers and distributors of opioids would have anticipated the scourge of opioid addiction and death, especially when being warned and prosecuted by law enforcement repeatedly. These Marketing and Distributor Defendants are required to exercise a high degree of care and diligence to prevent injury to the public from the diversion of highly dangerous opioid drugs during manufacture and distribution.

II. The Marketing and Distributor Defendants Breached Their Duty of Care

A. Marketing and Distributor Defendants' Conduct, in Violation of Applicable Statutes, Constitutes Negligence *Per Se*

963. The Marketing and Distributor Defendants' conduct, in violation of applicable statutes and regulations (including but not necessarily limited to laws regulating pharmacies, food and drugs, and the distribution of controlled substances), including but not limited to those statutes identified in Section VI, *supra*, constitutes negligence *per se*, and is actionable with or without an

affirmative finding by the trier of fact of a breach of the duty of care. State law and the CSA require that these Defendants know their customers, which includes an awareness of the customer base, knowledge of the average prescriptions filled each day, the percentage of controlled substances compared to overall purchases, a description of how the dispenser fulfills its responsibility to ensure that prescriptions filled are for legitimate medical purposes, and identification of physicians and bogus centers for the alleged treatment of pain that are the dispenser's most frequent prescribers.

964. The Marketing and Distributor Defendants violated both state law and federal laws in failing to report suspicious orders of opioid pain medications, in failing to maintain effective controls against the diversion of opioids into other than legitimate medical channels, and in failing to operate a system to stop or at least diligently respond to orders which is flagged or should have been flagged as suspicious. The Marketing and Distributor Defendants negligently acted with others by dispensing controlled substances for illegitimate medical purposes, operating bogus pain clinics which do little more than provide prescriptions for controlled substances, thereby creating and continuing addictions to prescription medications.

965. Plaintiffs are within the class of persons the state public safety laws and the CSA was intended to protect.

966. The harm that has occurred is the type of harm that the state public safety laws and the CSA was intended to guard against.

967. The Marketing and Distributor Defendants' violations constitute negligence *per se*.

B. Marketing and Distributor Defendants Breached Their Duty of Reasonable Care

968. Alternatively, to the extent that Marketing and Distributor Defendants' statutory violations do not obviate the need to show breaches of the duty of care, each Defendant breached its aforesaid duties of care.

1. Negligent Marketing

969. The Marketing Defendants marketed opioids in a negligent and improper manner by:

- a. Overstating the benefits of chronic opioid therapy, promising improvement in patients' function and quality of life, and failing to disclose the lack of evidence supporting long-term use;
- b. Trivializing or obscuring opioids' serious risks and adverse outcomes, including the risk of addiction, overdose and death;
- c. Overstating opioids' superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives;
- d. Mischaracterizing the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms;
- e. Marketing opioids for indications and benefits that were outside of the opioids' labels and not supported by substantial evidence.

It was Defendants' marketing – and not any medical breakthrough – that rationalized prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse. The result has been catastrophic.

970. The Marketing Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements indirectly, through KOLs and Front Groups, and in unbranded marketing materials. These KOLs and Front Groups were important elements of Defendants' marketing plans, which specifically contemplated their use, because they seemed independent and therefore outside FDA oversight. Through unbranded materials, Marketing Defendants, with their own knowledge of the risks, benefits and advantages of opioids, presented information and instructions concerning opioids generally that were contrary to, or at best, inconsistent with information and instructions listed on Marketing Defendants' branded marketing materials and drug labels. Marketing Defendants did so knowing that unbranded materials typically are not submitted to or reviewed by the FDA.

971. The Marketing Defendants also marketed opioids through the following vehicles: (a) KOLs, who could be counted upon to write favorable journal articles and deliver supportive CMEs; (b) a body of biased and unsupported scientific literature; (c) treatment guidelines; (d) CMEs; (e) unbranded patient education materials; and (f) Front Group patient-advocacy and professional organizations, which exercised their influence both directly and through Defendant-controlled KOLs who served in leadership roles in those organizations.

2. Negligent Distribution

972. The Marketing and Distributor Defendants distributed opioids in an improper manner by:

- a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;
- b. Distributing and selling opioids without maintaining effective controls against diversion;
- c. Choosing not to or failing to effectively monitor for suspicious orders;
- d. Choosing not to or failing to report suspicious orders;
- e. Choosing not to or failing to stop or suspend shipments of suspicious orders; and
- f. Distributing and selling opioids prescribed by “pill mills” when Marketing and Distributor Defendants knew or should have known the opioids were being prescribed by “pill mills.”

3. The Marketing and Distributor Defendants' Breaches of Care Were Intentional, Willful, Wanton and/or Reckless

973. Marketing and Distributor Defendants' breaches of care were intentional, willful, wanton and/or reckless. Marketing and Distributor Defendants purposely overstated the benefits of chronic opioid therapy and opioids' superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives; actively and continuously promoted the use of opioids for improvement in patients' function and quality of life but failed to

disclose the lack of evidence supporting the long-term use, as well as mischaracterized the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms; intentionally trivialized or obscured opioids' serious risks and adverse outcomes, including the risk of addiction, overdose, and death; continuously marketed opioids for indications and benefits that were outside of the opioids' labels and not supported by substantial evidence. Marketing and Distributor Defendants have willfully turned a blind eye towards the actual facts by regularly distributing large quantities of controlled substances to retailers and dispensers who are serving a customer base substantially comprised of individuals who are abusing and/or diverting prescription medications, many of whom are addicted and all of whom can reasonably be expected to become addicted. Marketing and Distributor Defendants conducted themselves with reckless indifference to the consequences of their acts and omissions, in that they were conscious of their conduct and were aware, from their knowledge of existing circumstances and conditions, that their conduct would inevitably or probably result in injury to others, specifically hospitals such as Plaintiffs, which would be subjected to providing unreimbursed healthcare treatment to patients with opioid conditions, as well as other costs associated with diagnosis, treatment of opioid-related conditions and operation of its business in the opioid epidemic.

C. Causation and Damages

974. As a direct and proximate result of Marketing and Distributor Defendants' conduct, Marketing and Distributor Defendants have caused Plaintiffs' injury related to the diagnosis and treatment of opioid-related conditions. Plaintiffs have incurred massive costs by providing uncompensated care as a result of opioid-related conditions.

975. The Purdue Individual Defendants, who are officers, directors and/or equity holders of Purdue and affiliates, directed and participated in the tortious conduct of Purdue and are individually liable.

976. The injuries to Plaintiffs would not have happened in the ordinary course of events had Marketing and Distributor Defendants exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of its business in the manufacture, marketing, sale and distribution of opioids.

977. Plaintiffs are entitled to recover compensatory damages as a result of Marketing and Distributor Defendants' negligence, in an amount to be determined at trial.

978. As a result of Marketing and Distributor Defendants' intentional, willful, wanton and/or reckless conduct described herein, Plaintiffs are entitled to treble, punitive, exemplary and/or otherwise enhanced damages to the full extent available under state law, in an amount to be determined at trial.

FOURTH CLAIM FOR RELIEF

Nuisance (Against All Defendants)

979. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

980. This claim is brought under the state common law of nuisance.

981. Plaintiff St. Vincent seeks only injunctive relief. The other Plaintiffs seek injunctive relief and damages.

982. The nuisance created by Defendants is the over-saturation of opioids in the patient population of Plaintiffs and in the geographic areas served by Plaintiffs for illegitimate purposes, as well as the adverse social, economic, and human health outcomes associated with widespread illegal opioid use.

983. Defendants, individually and acting through their employees and agents, through fraudulent and deceptive marketing and other fraudulent schemes as described herein, created and

maintained the opioid epidemic in Plaintiffs' communities, which is harmful and disruptive to and substantially and unreasonable annoys, injuriously affects, endangers, and interferes with the safety, health, morals, comfort, life, and general welfare of the public.

984. Defendants' nuisance-causing activities include selling or facilitating the sale of prescription opioids to the patients of Plaintiffs, as well as to unintended users, including children, people at risk of overdose or suicide, and criminals.

985. Defendants' nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of controlled substances, and their failure to adequately design and operate a system to detect, halt and report suspicious orders of controlled substances.

986. Defendants' activities unreasonably interfere with Plaintiffs' economic rights and the reasonable use of Plaintiffs' property. Plaintiffs' resources are being unreasonably consumed in efforts to address the opioid epidemic, thereby eliminating available resource which could be used to benefit the community within the geographic areas served by Plaintiffs as well as other health care areas.

987. The Defendants' interference with these rights of Plaintiffs are unreasonable because it:

- a. Has harmed and will continue to harm the public health services of and public peace of Plaintiff;
- b. Has harmed and will continue to harm the communities and neighborhoods which Plaintiffs serves;
- c. Is proscribed by statutes and regulation, including the CSA and the TDCA;
- d. Is of a continuing nature and it has produced long-lasting effects;
- e. Defendants have reason to know their conduct has a significant effect upon Plaintiff; and

f. Has inflicted substantial costs on Plaintiffs.

988. The nuisance undermines public health, quality of life, and safety. It has resulted in high rates of addiction, overdoses, dysfunction, death, and despair within families and entire communities. It has created a public health crisis.

989. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately recognized societal interest in facilitating widespread opioid addiction and failing to identify, halt, and report suspicious opioid transactions.

990. Defendants knew of the public health hazard their conduct would create. It was foreseeable to Defendants that their conduct would unreasonably interfere with the ordinary comfort, use, and enjoyment of residents in the communities in which Plaintiffs operate.

991. Defendants' conduct is unreasonable, intentional, unlawful, reckless, and/or negligent.

992. At all times, all Defendants possessed the right and ability to control the nuisance causing outflow of opioids from pharmacy locations or other points of sale. Distributor Defendants had the power to shut off the supply of illicit opioids to Plaintiffs and in the geographic areas served by Plaintiffs.

993. As a direct and proximate result of the nuisance, Plaintiffs have sustained economic harm by spending a substantial amount of money trying to remedy the harms caused by Defendants' nuisance-causing activity, including, but not limited to, costs of hospital services and healthcare. In short, the Defendants created a mess, leaving to the Plaintiffs and other hospitals the costs of cleaning it up. This is a classic nuisance.

994. As a result of Defendants' actions, Plaintiffs have suffered a special injury, different from that suffered by the public at large by individual users and by governmental entities, namely that Plaintiffs have provided uncompensated care for patients suffering from opioid-related conditions.

995. The public nuisance – i.e. the opioid epidemic – created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated.

996. Defendants should be required to pay the expenses Plaintiffs have incurred or will incur in the future to fully abate the nuisance.

997. The Purdue Individual Defendants, who are officers, directors and/or equity holders of Purdue and affiliates, directed and participated in the tortious conduct of Purdue and are individually liable.

998. Therefore, Plaintiffs demand judgment in their favor against the Defendants for injunctive relief, abatement of the public nuisance, and for damages in an amount to be determined by a jury, together with all cost of this action, including prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

FIFTH CLAIM FOR RELIEF

Unjust Enrichment (Against All Defendants)

999. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

1000. This claim is brought under the state common law of unjust enrichment.

1001. Plaintiffs provided unreimbursed healthcare treatment to patients with opioid-related conditions that Defendants are responsible for creating. Plaintiffs thereby conferred a benefit on Defendants because Defendants should bear the expense of treating these patients' opioid conditions. This is because Defendants created the opioid epidemic and the patients' opioid conditions, as described above.

1002. Defendants appreciated and knew of this benefit because they knew their opioid promotional and marketing policies would cause, and in fact have caused, hospitals throughout the United States to provide unreimbursed healthcare treatment to patients with opioid-related conditions that Defendants were responsible for creating.

1003. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the opioid epidemic.

1004. Plaintiffs purchased and continue to purchase opioid products marketed and sold by Defendants. Defendants directly marketed their opioid products through false, deceptive, and unfair marketing of opioid products purchased by Plaintiffs, its pharmacy representatives, and its doctors.

1005. Defendants have received and continue to receive the benefit of the false, deceptive, and unfair marketing and sales of their opioid products directly to Plaintiffs, their pharmacy representatives, and their doctors.

1006. The circumstances under which Defendants accepted or retained the benefit, described above, were such as to make it inequitable for Defendants to retain the benefit without payment of its value.

1007. As described above, the benefit was received and retained under such circumstances that it would be inequitable and unconscionable to permit Defendants to avoid payment therefor.

1008. Defendants have therefore been unjustly enriched at the expense of Plaintiffs.

1009. By reason of the foregoing, Defendants must disgorge their unjustly acquired proceeds and other monetary benefits, including income, salaries and bonuses, resulting from its unlawful conduct and provide restitution to the Plaintiffs.

SIXTH CLAIM FOR RELIEF

FRAUD AND DECEIT (Against All Defendants)

1010. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

1011. This claim is brought under the state common law of fraud and deceit.

1012. As alleged herein, Defendants violated their duty not to actively deceive by intentionally and unlawfully making knowingly false statements, and by intentionally and unlawfully omitting and/or concealing information.

1013. Defendants made misrepresentations and failed to disclose material facts to physicians and consumers throughout the United States, to induce the physicians to prescribe and administer, and consumers to purchase and consume, opioids as set forth herein.

1014. Specifically, the Marketing Defendants' knowingly deceptions during the relevant period, which were intended to induce reliance, include but are not limited to:

- a. Marketing Defendants' misrepresentations overstating the benefits of, and evidence for, the use of opioids in chronic pain;
- b. Marketing Defendants' misrepresentations that the risks of long-term opioid use, especially the risk of addiction, were overblown;

- c. Marketing Defendants' misrepresentations that opioid doses can be safely and effectively increased until pain relief is achieved;
- d. Marketing Defendants' misrepresentations that signs of addiction were "pseudoaddiction" and thus reflected undertreated pain, which should be responded to with more opioids;
- e. Marketing Defendants' misrepresentations that screening tools effectively prevent addiction;
- f. Marketing Defendants' misrepresentations concerning the comparative risks of NSAIDs and opioids;
- g. Marketing Defendants' misrepresentations that opioids differ from NSAIDs in that opioids have no ceiling dose;
- h. Marketing Defendants' misrepresentations that evidence supports the long-term use of opioids for chronic pain;
- i. Marketing Defendants' misrepresentations that chronic opioid therapy would improve patients' function and quality of life;
- j. Marketing Defendants' false portrayal of their efforts and/or commitment to rein in the diversion and abuse of opioids;
- k. Marketing Defendants' misrepresentations that withdrawal is easily managed;
- l. Purdue's and Endo's misrepresentations that alleged abuse-deterrent opioids reduce tampering and abuse;
- m. Purdue's misrepresentations that OxyContin provides a full 12 hours of pain relief;
- n. Purdue's misrepresentations that it cooperates with and supports efforts to prevent opioid abuse and diversion;
- o. Mallinckrodt's misrepresentations that it meets or exceeds legal requirements for controlling against diversion of controlled substances it has been entrusted to handle;
- p. Insys's misrepresentations that Subsys was appropriate for treatment of non-cancer pain and its failure to disclose that Subsys was not approved for such use;

- q. Insys's misrepresentations to third-party payors to secure approval for coverage;
- r. Insys's use of speaker bureaus to disguise kickbacks to prescribers;
- s. Teva's misrepresentations that Actiq and Fentora were appropriate for treatment of non-cancer pain and its failure to disclose that Actiq and Fentora were not approved for such use;
- t. Cephalon's unsubstantiated claims that Actiq and Fentora were appropriate for treatment of non-cancer pain;
- u. Marketing Defendants' use of front groups to misrepresent that the deceptive statements from the sources described in this Complaint came from objective, independent sources;
- v. Marketing Defendants' creation of a body of deceptive, misleading and unsupported medical and popular literature, advertisements, training materials, and speaker presentations about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors; and,
- w. Such other misrepresentations and deceptions outlined in the complaint.

1015. By engaging in the acts and practices alleged herein, Marketing Defendants, in the relevant time period and with the intent that others rely on their omissions or suppression of information, omitted material facts that Marketing Defendants had a duty to disclose by virtue of these Defendants' other representations, including but not limited to:

- a. Opioids are highly addictive and may result in overdose or death;
- b. No credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;
- c. High dose opioids subject the user to greater risks of addiction, other injury, and/or death;
- d. Opioids present the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, dizziness, increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines; these omissions were made while Defendants exaggerated the risks of competing products such as NSAIDs;

- e. Claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;
- f. Purdue's 12-hour OxyContin fails to last a full twelve hours in many patients;
- g. Purdue and Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the common route of abuse (oral), can be defeated with relative ease, and may increase overall abuse;
- h. Marketing Defendants' failure to report suspicious prescribers and/or orders;
- i. Insys's use of kickback and insurance fraud schemes;
- j. Insys's failure to disclose that Subsys was not approved for non-cancer pain;
- k. Cephalon's failure to disclose that Actiq and Fentora were not approved for non-cancer pain;
- l. Marketing Defendants' failure to disclose their financial ties to and role in connection with KOLs, front groups, and deceptive literature and materials, as more fully described above; and
- m. Such other omissions and concealments as described above in this Complaint.

1016. In each of the circumstances described *inter alia* the foregoing paragraphs, Marketing Defendants knew that their failure to disclose rendered their prior representations untrue or misleading.

1017. In addition, and independently, Marketing Defendants had a duty not to deceive Plaintiffs because Defendants had in their possession unique material knowledge that was unknown, and not knowable, to Plaintiffs, their agents, their communities, physicians, and the public.

1018. Marketing Defendants intended and had reason to expect under the operative circumstances that Plaintiffs, their agents, their communities, physicians, and persons on whom Plaintiffs and their agents relied would be deceived by Defendants' statements, concealments, and conduct as alleged herein and that Plaintiffs would act or fail to act in reasonable reliance thereon.

1019. Marketing Defendants intended that Plaintiffs, their agents, their communities, physicians, and persons on whom Plaintiffs and their agents relied would rely on these Defendants' misrepresentations and omissions; Defendants intended and knew that this reasonable and rightful reliance would be induced by these Defendants' misrepresentations and omissions; and, Defendants intended and knew that such reliance would cause Plaintiffs to suffer loss.

1020. The Marketing Defendants were not alone in this, the Distributor Defendants were also knowingly deceptive during the relevant period, and their deception was intended to induce reliance. These deceptions include but are not limited to:

- a. Acknowledgment of the Distributor Defendants by and through their front group, the HDMA, that distributors are at the center of a sophisticated supply chain and therefore, are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers;
- b. Acknowledgment of the Distributor Defendants that because of their unique position within the "closed" system, they were to act as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market;
- c. Cardinal Health claims to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse;"
- d. AmerisourceBergen took a same position as its counterpart within the industry and stated that it was "work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare to help find solutions that will support appropriate access while limiting misuse of controlled substances;"
- e. More holistically, Distributor Defendants misrepresented that not only do its members (Distributor Defendants) have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society; and
- f. Such other omissions or concealments as described above in this Complaint.

1021. By engaging in the acts and practices alleged herein, Distributor Defendants, in the relevant time period and with the intent that others rely on their omissions or suppression of

information, omitted material facts that Distributor Defendants had a duty to disclose by virtue of these Defendants' other representations, including but not limited to:

- a. There being no legitimate medical purpose for the copious amounts of opioids shipped into and around Plaintiffs' communities;
- b. That they failed to report to the DEA suspicious orders;
- c. That they failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical scientific and industrial channels by sales to certain customers;
- d. That they failed to prevent against diversion from legitimate to non-legitimate channels;
- e. That they failed to conduct meaningful due diligence to ensure that controlled substances were not diverted into other than legitimate channels;
- f. That they failed to keep and maintain accurate records of Schedule II – V controlled substances; and
- g. Such other omissions or concealments as alleged above in this Complaint.

1022. Distributor Defendants intended and had reason to expect under the operative circumstances that Plaintiffs, their agents, their communities, physicians, and persons on whom Plaintiffs relied would be deceived by Defendants' statements, concealments, and conduct as alleged herein and that Plaintiffs would act or fail to act in reasonable reliance thereon.

1023. Distributor Defendants intended that Plaintiffs, their agents, their communities, physicians, and persons on whom Plaintiffs and their agents relied would rely on these Defendants' misrepresentations and omissions; Defendants intended and knew that this reasonable and rightful reliance would be induced by these Defendants' misrepresentations and omissions; and, Defendants intended and knew that such reliance would cause Plaintiffs to suffer loss.

1024. Plaintiffs rightfully, reasonably, and justifiably relied on Marketing Defendants' representations and/or concealments, both directly and indirectly. As the Marketing Defendants

knew or should have known Plaintiffs were directly and proximately injured as a result of this reliance, Plaintiffs' injuries were directly and proximately caused by this reliance.

1025. As a result of these representations and/or omissions, Plaintiffs proceeded under the misapprehension that the opioid crisis was simply a result of conduct by persons other than Defendants. As a consequence, these Defendants prevented Plaintiffs from a timelier and effective response to the opioid epidemic.

1026. Defendants' false representations and omissions were material and were made and omitted intentionally and recklessly.

1027. Defendants' misconduct alleged in this case is ongoing and persistent.

1028. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort Plaintiffs would reasonably expect to occur and is not part of the normal and expected costs of a hospital's healthcare services. Plaintiffs allege wrongful acts which are neither discrete nor of the sort a hospital can reasonably expect.

1029. The Purdue Individual Defendants, who are officers, directors and/or equity holders of Purdue and affiliates, directed and participated in the tortious conduct of Purdue and are individually liable.

1030. Plaintiffs have incurred expenditures for special programs over and above ordinary hospital healthcare services.

1031. These Defendants' conduct was accompanied by wanton and willful disregard of person who foreseeably might be harmed by their acts and omissions.

1032. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

1033. Plaintiffs have suffered monetary damages as aforesaid. As such Plaintiffs seek all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of proceeds, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants. Attorney fees and costs, and pre- and post-judgment interest.

SEVENTH CLAIM FOR RELIEF

**Civil Conspiracy
(Against All Defendants)**

1034. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

1035. Plaintiffs bring this claim under state common law providing for the civil liability of persons who conspire to commit one or more unlawful acts.

1036. Defendants engaged in a common design between two or more persons to accomplish by concerted action an unlawful purpose, or a lawful purpose by unlawful means, an overt act in furtherance of the conspiracy, and resulting injury to Plaintiffs.

1037. Defendants engaged in a combination and an agreement to act in concert in their tortious and/or otherwise unlawful marketing of opioids and/or distribution of opioids in Plaintiffs' communities.

1038. Defendants engaged in one or more unlawful overt acts and activities as prohibited by law to further the conspiracy. The objects of the conspiracy were nuisance, negligence, fraud, misrepresentation, violation of state law, and other unlawful conduct as described above in this Complaint. Defendants knew that these objects were unlawful and would be accomplished by unlawful means such as fraud, misrepresentations, and omissions.

1039. Defendants each conspired with various KOLs and Front Groups to commit unlawful or lawful acts in an unlawful manner. Defendants and the various KOLs and Front Groups

with which each of them was allied, knowingly and voluntarily agreed to engage in unfair and deceptive practices to promote and distribute opioids for the treatment of chronic pain by making and disseminating false, unsubstantiated, and misleading statements and misrepresentations to prescribers and consumers. Defendants enlisted various KOLs and Front Groups to make and disseminate these statements in furtherance of their common strategy to increase the sale and distribution of opioids, and Defendants—along with the KOLs and Front Groups with whom each of them conspired—knew that the statements they made and disseminated served this purpose.

1040. By engaging in the conduct described in this Complaint, Defendant Cephalon agreed with Front Groups FSMB and APF that they would deceptively promote the risks, benefits and superiority of opioid therapy. As part of its agreements with FSMB and APF, Cephalon provided support for FSMB's and APF's deceptive statements promoting opioids and FSMB and APF used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Cephalon's drugs. *Responsible Opioid Prescribing* (Cephalon and FSMB) and *Treatment Options: A Guide for People Living with Pain* (Cephalon and APF) are publications that contained a number of deceptive statements about opioids as outlined *supra*. They are products of these conspiracies, and the collaboration between Cephalon and each of these entities in creating and disseminating these publications is further evidence of each conspiracy's existence.

1041. By engaging in the conduct described in this Complaint, Defendant Endo agreed with Front Groups APF, NICP, AGS and FSMB that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with APF, NICP, AGS and FSMB, Endo provided support for APF, NICP, AGS and FSMB's deceptive statements promoting opioids and APF, NICP, AGS and FSMB used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Endo's drugs. *Persistent Pain in the Older*

Adult (Endo, APF, and NIPC), *Persistent Pain in the Older Patient* (Endo, APF, and NIPC), *Painknowledge.com* (Endo, APF, and NIPC), *Exit Wounds* (Endo and APF), *Pharmacological Management of Persistent Pain in Older Persons* (Endo and AGS), and *Responsible Opioid Prescribing* (Endo and FSMB) are publications, CMEs, and websites that contained a number of deceptive statements about opioids as outlined *supra*. They are products of these conspiracies, and the collaboration between Endo and each of these entities in creating and disseminating these publication, CMEs, and websites is further evidence of each conspiracy's existence.

1042. By engaging in the conduct described in this Complaint, Defendant Janssen agreed with Front Groups AAPM, AGS and APF that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with AAPM, AGS, and APF, Janssen provided support for AAPM, AGS, and APF's deceptive statements promoting opioids and Conrad & Associates LLC, Medical Writer X, AAPM, AGS, and APF used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Janssen's drugs. *Finding Relief: Pain Management for Older Adults* (Janssen, AAPM, and AGS), a CME promoting the *Pharmacological Management of Persistent Pain in Older Persons* (Janssen and APF), the *Let's Talk Pain* website (Janssen and APF), and *Exit Wounds* (Janssen and APF) are publications, CMEs, and websites that contained a number of deceptive statements about opioids as outlined *supra*. They are products of these conspiracies and the collaboration between Janssen and each of these entities in creating and disseminating these publications is further evidence of each conspiracy's existence.

1043. By engaging in the conduct described in this Complaint, Defendant Purdue agreed with Front Groups APF, FDMB, and AGS that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with APF, FSMB, and AGS, Purdue

provided support for APF, FSMB, and AGS's deceptive statements promoting opioids and APF, FSMB, and AGS used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Purdue's drugs. The *Partners Against Pain* website (Purdue and APF), *A Policymaker's Guide to Understanding Pain & Its Management* (Purdue and APF), *Treatment Options: A Guide for People Living with Pain* (Purdue and APF), *Exit Wounds* (Purdue and APF),³⁶¹ *Responsible Opioid Prescribing* (Purdue and FSMB), and a CME promoting the *Pharmacological Management of Persistent Pain in Older Persons* (Purdue and AGS) are publications, CMEs, and websites that contained a number of deceptive statements about opioids as outlined *supra*. They are products of these conspiracies, and the collaboration between Purdue and each of these entities in creating and disseminating these publications, CME's and websites is further evidence of each conspiracy's existence.

1044. Each of the participants to the conspiracies outlined above was aware of the misleading nature of the statements they planned to issue and of the role they played in each scheme to deceptively promote opioids as appropriate for the treatment of chronic pain. These Defendants and third parties nevertheless agreed to misrepresent the risks, benefits, and superiority of using opioids to Plaintiffs in return for increased pharmaceutical sales, financial contributions, reputational enhancements, and other benefits.

1045. Each of the participants to the conspiracies outlined above was aware of the nuisance resulting from their conduct, and agreed to continue the practices described above that resulted in the maintenance of that nuisance.

³⁶¹ Purdue's collaboration with APF through APF's "Corporate Roundtable" and Purdue and APF's active collaboration in running PCF constitute additional evidence of the conspiracy between Purdue and APF to deceptively promote opioids.

1046. Distributor Defendants utilized their membership in the HDA and other forms of collaboration to form agreements about their approach to their duties under the CSA to report suspicious orders. The Defendants overwhelmingly agreed on the same approach – to fail to identify, report or halt suspicious opioid orders, and fail to prevent diversion. Defendants' agreement to restrict reporting provided an added layer of insulation from DEA scrutiny for the entire industry as Defendants were thus collectively responsible for each other's compliance with their reporting obligations. Defendants were aware, both individually and collectively aware of the suspicious orders that flowed directly from Defendants' facilities.

1047. Defendants knew that their own conduct could be reported by other Defendants and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting or suspicious orders to ensure consistency in their dealings with DEA.

1048. The Defendants also worked together to ensure that the opioid quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

1049. The Defendants further worked together in their unlawful failure to act to prevent diversion and failure to monitor for, report, and prevent suspicious order of opioids.

1050. The desired consistency, and collective end goal was achieved. Defendants achieved higher profits through higher opioid sales by orchestrating the unimpeded flow of opioids.

1051. By reason of Defendants' unlawful acts, Plaintiffs have been damaged and continue to be damaged by paying the costs of Defendants' externalities and have suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain.

1052. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, acted purposely, without a reasonable or lawful excuse, which directly caused the injuries alleged herein.

1053. Defendants acted with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse.

1054. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

1055. As outlined above, Defendants played an active role in determining the substance of the misleading messages issued by KOLs and Front Groups, including by providing content themselves, editing and approving content developed by their co-conspirators, and providing slide decks for speaking engagements. Defendants further ensured that these misstatements were widely disseminated, by both distributing the misstatements themselves and providing their co-conspirators with funding and other assistance with distribution. The result was an unrelenting stream of misleading information about compliance with state and federal legislation as related to opioid distribution, and the risks, benefits, and superiority of using opioids to treat chronic pain from sources Defendants knew were trusted by prescribers and consumers. Defendants exercised direct editorial control over most of these statements. However, even if Defendants did not directly disseminate or control the content of these misleading statements, they are liable for conspiring with the third parties who did.

1056. Defendants conduct in furtherance of the conspiracy described herein was not mere parallel conduct because each Defendant acted directly against their commercial interests in not reporting the unlawful distribution practices of their competitors to the authorities, which they had a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an actual or tacit agreement between the Defendants that they would not report each other to the authorities so they could all continue to engage in their unlawful conduct.

1057. Defendants had a meeting of the minds on the object of or course of action for this conspiracy. Defendants knew and agreed upon the unlawful object or course of action for this conspiracy. Defendants also knew that their wrongful actions would inflict injury upon the targets of the conspiracy, including Plaintiffs.

1058. Defendants' conspiracy, and Defendants' actions and omissions in furtherance thereof, caused the direct and foreseeable losses alleged herein.

1059. Defendants' misconduct alleged in this case is ongoing and persistent.

1060. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergent of the sort a hospital would reasonably expect to occur and is not part of the normal and expected costs of a hospital's healthcare services. Plaintiffs allege wrongful acts which are neither discrete nor of the sort a hospital can reasonably expect.

1061. Plaintiffs have incurred expenditures for special programs over and above ordinary healthcare services.

1062. Because of Defendants dissemination of false information and misleading information of opioid risks, benefits, and sustainability for chronic pain, and false and misleading statements regarding compliance with state law concerning the distribution of opioids, Defendants are responsible for the costs.

1063. Defendants conspired to create a public nuisance and to commit tortious conduct and are therefore jointly and severally liable for the damages flowing from the conspiracy.

1064. Plaintiffs therefore request this Court to enter an order awarding judgment in their favor against Defendants, compelling Defendants to pay the direct and consequential damages, and awarding Plaintiffs such other, further, and different relief as this Court may deem just and proper.

EIGHTH CLAIM FOR RELIEF

Violation of Statutes Prohibiting Unfair and Deceptive Acts in Trade or Commerce (By Plaintiffs Against All Defendants)

1065. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

1066. As alleged herein, and upon information and belief, Defendants committed unfair, false, misleading, and/or deceptive acts with regard to the sale and distribution of opioids in violation of the various state statutes (the “UDAP Statutes”³⁶²) prohibiting unfair and/or deceptive

³⁶² The UDAP Statutes are:

Deceptive Trade Practices Act, Ala. Code §§ 8-19-1 *et seq.*; Unfair Trade Practices and Consumer Protection Act, Alaska Stat. §§ 45.50.471 *et seq.*; Consumer Fraud Act, Ariz. Rev. Stat. Ann. §§ 44-1521 *et seq.*; Deceptive Trade Practices Act, Ark. Code Ann. §§ 4-88-101 *et seq.*; Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200 *et seq.* (West); Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750 *et seq.* (West); Consumer Protection Act, Colo. Rev. Stat. §§ 6-1-101 *et seq.*; Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. §§ 42-110a *et seq.*; D.C. Code §§ 28-3901 *et seq.*; Consumer Fraud Act, Del. Code Ann. tit. 6, §§ 2511 *et seq.*, 2580 *et seq.*; Deceptive and Unfair Trade Practices Act, Fla. Stat. §§ 501.201 *et seq.*; Fair Business Practices Act, Ga. Code Ann. §§ 10-1-390 *et seq.*; Haw. Rev. Stat. §§ 480-1 *et seq.*; Consumer Protection Act, Idaho Code Ann. §§ 48-601 *et seq.*; Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. 505-1 *et seq.*; Deceptive Consumer Sales Act, Ind. Code §§ 24-5-0.5-1 *et seq.*; Consumer Protection Act, Kan. Stat. Ann. §§ 50-623 *et seq.*, 50-675a *et seq.*; Consumer Protection Act, Ky. Rev. Stat. Ann. §§ 367.110 *et seq.* (West); Unfair Trade Practices and Consumer Protection Law, La. Rev. Stat. Ann. §§ 51:1401 *et seq.*; Unfair Trade Practices Act, Me. Rev. Stat. Ann. tit. 5, §§ 205A *et seq.*; Maryland Consumer Protection Act, Md. Code Ann., Com. Law §§ 13-101 *et seq.* (West); Regulation of Business Practice and

acts in trade or commerce. The claims of the Plaintiffs are governed by the UDAP statutes³⁶³ of the states in which they are located. Plaintiffs seek to represent a broader class of similarly situated persons in states with analogous statutes.

1067. Defendants engaged in deception, deceptive or unfair acts or practices, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of material

Consumer Protection Act, Mass. Gen. Laws Ann. ch. 93A, §§ 1 *et seq.*; Consumer Protection Act, Mich. Comp. Laws §§ 445.901 *et seq.*; Minn. Stat. § 8.31; False Statement in Advertising Act, Minn. Stat. § 325F.67; Prevention of Consumer Fraud Act, Minn. Stat. §§ 325F.68 *et seq.*; Consumer Protection Act, Miss. Code Ann. §§ 75-24-1 *et seq.*; Merchandising Practices Act, Mo. Rev. Stat. §§ 407.010 *et seq.*; Unfair Trade Practices and Consumer Protection Act, Mont. Code Ann. §§ 30-14-101 *et seq.*; Consumer Protection Act, Neb. Rev. Stat. §§ 59-1601 *et seq.*; Trade Regulation and Practices Act, Nev. Rev. Stat. §§ 598.0903 *et seq.*; Nev. Rev. Stat. § 41.600; Consumer Protection Act, N.H. Rev. Stat. Ann. §§ 358-A:1 *et seq.*; N.J. Stat. Ann. §§ 56:8-1 *et seq.* (West); Unfair Practices Act, N.M. Stat. §§ 57-12-1 *et seq.*; N.Y. Exec. Law § 63(12) (McKinney); N.Y. Gen. Bus. Law §§ 349 *et seq.* (McKinney); N.C. Gen. Stat. §§ 75-1.1 *et seq.*; N.D. Cent. Code §§ 51-15-01 *et seq.*; Consumer Sales Practices Act, Ohio Rev. Code Ann. §§ 1345.01 *et seq.* (West); Consumer Protection Act, Okla. Stat. tit. 15, §§ 751 *et seq.*; Unlawful Trade Practices Law, Or. Rev. Stat. §§ 646.605 *et seq.*; Unfair Trade Practices and Consumer Protection Law, 73 Pa. Stat. Ann. §§ 201-1 *et seq.* (West); Unfair Trade Practice and Consumer Protection Act, R.I. Gen. Laws §§ 6-13.1-1 *et seq.*; Unfair Trade Practices Act, S.C. Code Ann. §§ 39-5-10 *et seq.*; Deceptive Trade Practices and Consumer Protection Law, S.D. Codified Laws §§ 37-24-1 *et seq.*; Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101 *et seq.*; Deceptive Trade Practices--Consumer Protection Act, Tex. Bus. & Com. Code Ann. §§ 17.41 *et seq.* (Vernon); Consumer Sales Practices Act, Utah Code Ann. §§ 13-11-1 *et seq.*; Consumer Fraud Act, Vt. Stat. Ann. tit. 9, §§ 2451 *et seq.*; Consumer Protection Act, Va. Code Ann. §§ 59.1-196 *et seq.*; Consumer Protection Act, Wash. Rev. Code §§ 19.86.010 *et seq.*; W. Va. Code §§ 46A-6-101 *et seq.*; Wis. Stat. § 100.18 *et seq.*; Consumer Protection Act, Wyo. Stat. Ann. §§ 40-12-101 *et seq.*

Protection Act, Tenn. Code Ann. §§ 47-18-101 *et seq.*; Deceptive Trade Practices--Consumer Protection Act, Tex. Bus. & Com. Code Ann. §§ 17.41 *et seq.* (Vernon); Consumer Sales Practices Act, Utah Code Ann. §§ 13-11-1 *et seq.*; Consumer Fraud Act, Vt. Stat. Ann. tit. 9, §§ 2451 *et seq.*; Consumer Protection Act, Wash. Rev. Code §§ 19.86.010 *et seq.*; Wis. Stat. § 100.18 *et seq.*; Consumer Protection Act, Wyo. Stat. Ann. §§ 40-12-101 *et seq.*

³⁶³ Plaintiffs' own claims are governed, respectively, by (1) the Ohio Consumer Sales Practices Act, Ohio R.C. § 1345.01 *et seq.*, (2) the Alabama Deceptive Trade Practices Act, Ala. Code § 8-19-1 *et seq.*, and (3) the (Mississippi) Consumer Protection Act, Miss. Code Ann. §§ 75-24-1 *et seq.*

facts with the intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of prescription drugs in violation of the UDAP Statutes.

1068. During the relevant period and as detailed further herein, the Marketing Defendants have each engaged in unfair and deceptive acts or practices in commerce in violation of the UDAP Statutes by actively promoting and marketing the use of opioids for indications not federally approved, circulating false and misleading information concerning opioids' safety and efficacy, and downplaying or omitting the risk of addiction arising from their use.

1069. Each of the Defendants have engaged in unfair and/or deceptive trade practices by omitting the material fact of its failure to design and operate a system to disclose suspicious orders of controlled substances, as well as by failing to actually disclose such suspicious orders, as required of "registrants" by the federal CSA, 21 C.F.R. § 1301.74(b). The CSA defines "Registrant" as any person who is registered pursuant to 21 U.S.C. § 823. 21 C.F.R. § 1300.02(b). Section 823(a)-(b) requires manufacturers and distributors of controlled substances Schedule II to register.

1070. The products at issue are consumer products. The transactions at issue, that caused the distribution of those products, were entirely, or at least in principal part, consumer transactions.

1071. Defendants' unfair or deceptive acts or practices in violation of the UDAP Statutes also offend these states' public policy, and are immoral, unethical, oppressive and unscrupulous, as well as malicious, wanton and manifesting of ill will, and they caused substantial injury to Plaintiffs. Plaintiffs risk irreparable injury as a result of the Marketing and Distributor Defendants', and their agents', acts, misrepresentations, and omissions in violation of the UDAP Statutes, and these violations present a continuing risk to Plaintiffs, as well as to the general public.

1072. Defendants' conduct constitutes both "unfair" and "deceptive" acts and practices affecting the conduct of trade or commerce.

1073. As a direct and proximate result of Defendants' violations, Plaintiffs have suffered and continues to suffer injury-in-fact and actual damages.

1074. Defendants violated the foregoing statutes because they engaged in false or misleading statements about the efficacy and safety of opioid pharmaceuticals.

1075. Defendants, individually and acting through their employees and agents, and in concert with each other, knowingly made material misrepresentations and omissions of facts to Plaintiffs to induce them to purchase and administer opioid pharmaceuticals, as set forth in detail above.

1076. Defendants knew at the time that they made their misrepresentations and omissions that they were false.

1077. Defendants intended that Plaintiffs, physicians, patients, and/or others would rely on their misrepresentations and omissions.

1078. Plaintiffs, physicians, patients, and/or others reasonably relied upon Defendants' misrepresentations and omissions.

1079. In the alternate, the Defendants recklessly disregarded the falsity of their representations regarding opioids.

1080. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, Plaintiffs, physicians, patients, and/or others suffered actual pecuniary damage.

1081. The Purdue Individual Defendants, who are officers, directors and/or equity holders of Purdue and affiliates, directed and participated in the tortious conduct of Purdue and are individually liable.

1082. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally.

1083. Plaintiffs have suffered an ascertainable loss of money or property and/or other things of value as a result of the use or employment by Defendants of unfair and/or deceptive acts or practices.

1084. Plaintiffs are entitled to recover its damages caused by Defendants' violation of the various state consumer protection statutes set forth below in an amount to be determined at trial, including treble and/or otherwise enhanced damages, to the full extent recoverable if the court finds that the use or employment of the unfair or deceptive act or practice was a willful and/or knowing violation, as well as attorneys' fees to the full extent recoverable.

1085. Plaintiffs also seek injunctive relief pursuant to the UDAP Statutes.

NINTH CLAIM FOR RELIEF

Violation of State RICO Statutes – Opioid False Narrative Enterprise (By Plaintiff St. Vincent Against the RICO-1 Defendants)

1086. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

1087. Plaintiff St. Vincent brings its own claim under Ohio's Pattern of Corrupt Activities Law, Ohio R.C. §§ 2923.31, *et seq.*, and seeks to represent similarly situated persons in states with analogous statutes ("State RICO" laws, collectively the "State RICO Statutes"³⁶⁴) that provide for

³⁶⁴ The State RICO Statutes applicable to claims of class members who reside in states providing for a private right of action are: Arizona Racketeering Act, Ariz. Rev. Stat. §§ 13-2301 *et seq.*; Colorado Organized Crime Control Act, Colo. Rev. Stat. Ann. §§ 18-17-101 *et seq.*; Florida RICO (Racketeer Influenced and Corrupt Organization) Act, Fla. Stat. Ann. §§ 895.01 *et seq.*; Georgia RICO (Racketeer Influenced and Corrupt Organizations) Act, Ga. Code Ann. §§ 16-14-1 *et seq.*; Hawaii Organized Crime Act, Haw. Rev. Stat. §§ 842-1 *et seq.*; Idaho Racketeering Act, Idaho Code §§ 18-7801 *et seq.*; Illinois Narcotics Profit Forfeiture Act, 725 Ill. Comp. Stat. Ann. 175/1 *et seq.*; Indiana Racketeer Influenced and Corrupt Organizations Act, Ind. Code Ann. §§ 35-45-6-1 *et seq.*; Iowa Ongoing Criminal Conduct ACT, Iowa Code §§ 706A.1 *et seq.*; Louisiana Racketeering Act, La. Rev. Stat. Ann. §§ 15:1351 *et seq.*; Nevada Racketeering Act, Nev. Rev. Stat. Ann. §§ 207.350 *et seq.*; New Jersey RICO (Racketeer Influenced and Corrupt Organizations) Act, N.J. Stat. Ann. §§ 2C:41-1 *et seq.*; New Mexico Racketeering Act, N.M.

civil claims for damages and injunctive relief arising from the conduct of racketeer-influenced and corrupt organizations.

1088. At all relevant times, the Plaintiffs were entities capable of holding a legal or beneficial interest in property, which means that it was a “person” within the meaning of the RICO Statutes.

1089. **Structure of the False Narrative Enterprise:** At all relevant times, Defendants, in violation of the law of the State RICO Statutes, conducted (managed) or participated, directly or indirectly, in the conduct (management) of the False Narrative Enterprise, through a pattern of unlawful or otherwise prohibited activity.

(1) **Name.** At all relevant times, there existed an “enterprise,” – to wit, an association-in-fact comprised of each of the Defendants – referred to herein as “The False Narrative Enterprise.”

(2) **Purposes.** The lawful purpose of the False Narrative Enterprise was the manufacture, marketing and sale of pharmaceutical products in interstate and foreign commerce. The unlawful purpose of the False Narrative Enterprise was to engage in and carry out an intentional scheme to defraud purchasers and others, including doctors and hospitals, by propagating falsehoods about the safety and benefits of opioids.

(3) **Continuity:** The continuity of the False Narrative Enterprise was coterminous with the period of time necessary to defraud Plaintiffs, other hospitals, physicians, other healthcare providers, patients and their families, and the American public in general.

Stat. Ann. §§ 30-42-1 *et seq.*; North Carolina Racketeer Influenced and Corrupt Organizations Act (RICO), N.C. Gen. Stat. §§ 75D-1 *et seq.*; North Dakota Racketeer Influenced and Corrupt Organizations Act, N.D. Cent. Code §§ 12.1-06.1-01 *et seq.*; Ohio Pattern of Corrupt Activities Act, Ohio Rev. Code Ann. §§ 2923.31 *et seq.*; Oregon Racketeer and Corrupt Organization Act, Or. Rev. Stat. §§ 166.715 *et seq.*; Rhode Island Racketeering and Corrupt Organizations Act, R.I. Gen. Laws § 7-15-1 *et seq.*; Puerto Rico Act Against Organized Crime and Money Laundering of the Commonwealth of Puerto Rico, 25 L.P.R.A. §§ 971 *et seq.*; Utah Pattern of Unlawful Activity Act, Utah Code Ann. §§ 76-10-1601 *et seq.*; Virginia Islands Criminally Influenced and Corrupt Organizations Act, 14 V.I.C. §§ 600 *et seq.*; Washington Criminal Profiteering Act, Wash. Rev. Code Ann. §§ 9A.82.001 *et seq.*; Wisconsin Organized Crime Control Act, Wis. Stat. §§ 946.80 *et seq.*

(4) **Effect on Commerce:** The False Narrative Enterprise was engaged in, and its activities affected, interstate and foreign commerce.

(5) **Membership:** The False Narrative Enterprise reflected several types of participants, not all of which were complicit, and not all of which are named herein as Defendants:

(a) **The Marketing Defendants.** The Marketing Defendants are Purdue, Actavis, Amneal, Cephalon, Janssen, Depomed, Endo, Insys, Abbot, and Mallinckrodt. The Marketing Defendants conceptualized and set in motion the falsehoods about opioids that created billions of dollars of artificial demand for these highly addictive and dangerous products.

(b) **The Front Groups.** The Marketing Defendants used the Front Groups, such as the American Pain Foundation, American Academy of Pain Medicine, the American Pain Society, the Federation of State Medical Boards, the Alliance for Patient Access, the U.S. Pain Foundation, the American Geriatrics Society, and the American Chronic Pain Association, not named as defendants herein and not all of which were fully complicit, to stoke demand for opioids by falsely creating the impression of independent third party authoritative validation of the false claims of the Marketing Defendants.

(c) **The KOLs.** The Marketing Defendants used KOLs, such as Dr. Portenoy, Dr. Webster, Dr. Fine and Dr. Fishman, not named as defendants herein and who may not have been fully complicit, to provide ostensibly valid, third party, authoritative validation of the false claims of the Marketing Defendants.

(d) **The Distributor Defendants.** The Distributor Defendants are Cardinal, Anda, H. D. Smith, Henry Schein, AmerisourceBergen and Miami-Lukan; they joined the False Narrative Enterprise with full awareness and complicity, and acted in concert with the Marketing Defendants to pool information about vulnerable targets and share the king size profits reaped from the sale of opioids to addicts, deliberately ignoring their obligations under the Controlled Substances Act.

(e) **Corrupt Physicians and Pharmacies, a/k/a the Pill Mills.** prescribed opioids illegally and with no basis in legitimate medicine; and dispensed opioids illegally and in direct violation of their legal obligations.

(f) **The National Retail Pharmacies.** The National Retail Pharmacies are CVS, Kroger, Rite-Aid, Walgreens, and Wal-Mart. Like the Distributor Defendants, they joined the False Narrative Enterprise with full awareness and complicity, and acted in concert with the Marketing Defendants to pool information about vulnerable targets and share the king size profits reaped

from the sale of opioids to addicts, deliberately ignoring their obligations under the Controlled Substances Act and state RICO laws.

1090. **Predicate Acts.** At all relevant times, Defendants conducted (managed) or participated, directly or indirectly, in the conduct (management) of the False Narrative Enterprise, through a pattern of unlawful activity. In addition to participating in a RICO-violative enterprise, the Defendants, with full knowledge and purpose, conspired to violate those provisions in the RICO Statutes prohibiting participation in unlawful or otherwise prohibited enterprises.³⁶⁵ Defendants did so by engaging in multiple, repeated, and continuous violations of:

(1) Wire fraud and other fraudulent practices: The Defendants transmitted communications, including advertisements, through U.S. mail fraud and interstate wire fraud, in interstate or foreign commerce, to designated persons for ostensibly legitimate purposes, but with the actual, unlawful purpose of engaging in an intentional scheme to defraud or mislead Plaintiffs, other hospitals, health care providers, patients and their families and, in general, the American public. Defendants engaged in a scheme or artifice to defraud and/or thereby knowingly obtained a benefit by means of false or fraudulent pretenses, representations, promises or material omissions.

(2) Violation of state controlled substances acts, including the Ohio Controlled Substances Act, Ohio R.C. § 3719.01 *et seq.*, the regulations promulgated thereunder, and other statutes and regulations governing the manufacture, distribution or sales of controlled substances. The Defendants engaged in manufacture, distribution or sales of controlled substances or narcotic drugs. The Defendants violated the applicable state law and statutes through their participation in the False Narrative Enterprise, and through their failure to monitor, report, or guard against suspicious orders and diversion of the controlled substances or narcotic drugs.

(3) Violation of federal criminal statutes (*See Count I, supra*).

1091. Defendants' predicate acts, enumerated above, constitute a "pattern of corrupt activity" as defined in Ohio R.C. § 2923.31 (as well as unlawful or otherwise prohibited activity

³⁶⁵ Defendants' management and participation in the enterprise as well as their conspiracy to conduct the unlawful activities violated Ohio R.C. § 2923.32(a)(1) and analogous provisions in laws of other states in which members of the Class are located.

as defined in the RICO Statutes, and a “pattern” of unlawful or otherwise prohibited activity, as defined in the federal and certain state RICO Statutes).

1092. At all relevant times, Defendants, in violation of the above statutes, conducted (managed) or participated, directly or indirectly, in the conduct (management) of the False Narrative Enterprise, through a pattern of unlawful activity, by engaging in multiple, repeated, and continuous predicate acts listed above.

1093. Defendants also conspired to engage in corrupt activity, constituting a conspiracy to violate RICO, in violation of state laws analogous to 18 U.S.C. § 1962(d).

1094. **Consequences.** By reason of the above-referenced violations of the state RICO Statutes, Plaintiffs were injured in their business or property, is entitled to assert this claim, and to recover threefold the damages they sustained, as demonstrated at trial, and the cost of the suit, including reasonable attorneys’ fees, as well as such other appropriate relief, as the Court may provide.

TENTH CLAIM FOR RELIEF

Violation of State RICO Statutes – Sackler Pharmaceutical Enterprise (By Plaintiff St. Vincent Against the Purdue Defendants)

1095. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

1096. Plaintiff St. Vincent brings its own claim under Ohio's Pattern of Corrupt Activities Law, Ohio R.C. §§ 2923.31, *et seq.*, and seeks to represent similarly situated persons in states with State RICO Statutes.

1097. At all relevant times, Plaintiffs were entities capable of holding a legal or beneficial interest in property, which means that it was a “person” within the meaning of the State RICO Statutes.

I. The Sackler Pharmaceutical Enterprise

1098. **Name, Purposes and Membership.** At all relevant times, there existed an “enterprise,” within the meaning of the State RICO Statutes – to wit, an association-in-fact comprised of each of the Purdue Defendants - the Sackler Pharma Enterprise. The lawful purpose of the Sackler Pharma Enterprise was the manufacture, marketing and sale of pharmaceutical products in interstate and foreign commerce. The unlawful purpose of the Sackler Pharma Enterprise was to engage in and carry out an intentional scheme to defraud purchasers, including doctors and hospitals, by propagating falsehoods about the safety and benefits of opioids.

1099. **Continuity:** The continuity of the Sackler Pharma Enterprise was coterminous with the period of time necessary to defraud Plaintiffs, other hospitals, physicians, other healthcare providers, patients and their families, and the American public in general.

1100. **Predicate Acts:** At all relevant times, Defendants engaged in multiple, repeated, and continuous violations of:

(1) Wire fraud and other fraudulent practices: The Defendants transmitted communications, including advertisements, through U.S. mail fraud and interstate wire fraud, in interstate or foreign commerce, to designated persons for ostensibly legitimate purposes, but with the actual, unlawful purpose of engaging in an intentional scheme to defraud or mislead Plaintiffs, other hospitals, health care providers, patients and their families and, in general, the American public. Defendants engaged in a scheme or artifice to defraud and/or thereby knowingly obtained a benefit by means of false or fraudulent pretenses, representations, promises or material omissions.

(2) Violation of state controlled substances acts, including the Ohio Controlled Substances Act, Ohio R.C. § 3719.01 *et seq.*, the regulations promulgated thereunder, and other statutes and regulations governing the manufacture, distribution or sales of controlled substances. The Defendants engaged in manufacture, distribution or sales of controlled substances or narcotic drugs. The Defendants violated the applicable state law and statutes through their participation in the False Narrative Enterprise, and through their failure to monitor, report, or guard against suspicious orders and diversion of the controlled substances or narcotic drugs.

(3) Violation of federal criminal statutes (*See Count II, supra*).

1101. Structure of the Purdue Pharma Enterprise: The Sackler Pharma Enterprise reflected several types of participants, not all of whom were complicit, and not all of which are named herein as Defendants:

- A. The Sackler Defendants.** The Sackler Defendants are Richard Sackler, Beverly Sackler, David Sackler, Ilene Sackler Lefcourt, Jonathan Sackler, Kathe Sackler, Mortimer Sackler, and Theresa Sackler controlled Purdue's misconduct. The Sackler Defendants conceptualized and set in motion the falsehoods about opioids that created billions of dollars of artificial demand for these highly addictive and dangerous products. Together, the Sackler Defendants directed and otherwise participated in Purdue's deceptive sales and marketing practices, sending hundreds of orders to executives and other employees. From the money that Purdue collected as a result of its wrongful conduct, they paid themselves and their family billions of dollars.
- B. The Other Purdue Directors:** The other members of Purdue's Board, at pertinent times, include Peter Boer, Judith Lewent, Paulo Costa and Ralph Snyderman. Although not named as defendants, they each joined and participated in the Sackler Pharma Enterprise with full awareness and complicity, acted in concert with the Sackler Defendants to direct Purdue's deception and/or carry out the misconduct and share the king size profits reaped from the sale of opioids to Plaintiffs, health care providers, patients and their families and, in general, the American public.
- C. The Purdue Officer Defendants:** The Purdue Officer Defendants are John Stewart, Mark Timney, Craig Landau and Russell Gasdia. The Purdue

Officer Defendants each joined and participated in the Sackler Pharma Enterprise with full awareness and complicity, acted in concert with the Sackler defendants to direct Purdue's deception and/or carry out the misconduct and share the king size profits reaped from the sale of opioids to Plaintiffs, health care providers, patients and their families and, in general, the American public.

D. The Purdue Entity Defendants and Other Affiliated Entities: The Purdue Entity Defendants are Purdue Pharma L.P., Purdue Pharma Inc. and The Purdue Frederick Company, Inc. The Purdue Entity Defendants, and other business entities beneficially owned and controlled by the Sackler Defendants not named as Defendants, joined the Sackler Pharma Enterprise with full awareness and complicity, and acted in concert with the Sackler Defendants to pool information about vulnerable targets and share the king size profits reaped from the sale of opioids to Plaintiffs, health care providers, patients and their families and, in general, the American public, deliberately ignoring duties to comply with laws and regulations on marketing and sales of controlled substances.

E. The Purdue Sales Representatives and Other Employees: These participants are not named as defendants herein and who may not have been fully complicit. The Purdue Sales Representatives implemented marketing and sales plans under the direction and control of the Sackler Defendants, the Purdue Director and Purdue Officer Defendants, including pooling information about vulnerable targets, increasing sales of highly addictive

opioids directly to Plaintiffs and physicians, concealing risks of opioids, as well as sharing the king size profits reaped from the sale of opioids to Plaintiffs, health care providers, patients and their families and, in general, the American public.

1102. Defendants' predicate acts, enumerated above, constitute a "pattern of corrupt activity" as defined in Ohio R.C. § 2923.31 (as well as unlawful or otherwise prohibited activity as defined in the other State RICO Statutes, and a "pattern" of unlawful or otherwise prohibited activity, as defined in the federal and certain State RICO Statutes).

1103. At all relevant times, Defendants, in violation of the above statutes, conducted (managed) or participated, directly or indirectly, in the conduct (management, if required by law) of the Sackler Pharma Enterprise, through a pattern of unlawful activity, by engaging in multiple, repeated, and continuous predicate acts listed above.

1104. Defendants also conspired to engage in corrupt activity, constituting a conspiracy to violate RICO, in violation of state laws analogous to 18 U.S.C. § 1962(d).

II. Consequences

1105. By reason of the above-referenced violations of the State RICO Statutes, Plaintiffs were injured in their business or property, are entitled to assert this claim, and to recover multiple damages as provided by law that they sustained, as demonstrated at trial, and the cost of the suit, including reasonable attorneys' fees, as well as such other appropriate relief, as the Court may provide.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask that the Court:

- A. Certify the Class proposed herein;
- B. Appoint Plaintiffs as representatives of the Class;

- C. Appoint Plaintiffs' counsel as attorneys for the Class;
- D. Award compensatory damages in an amount sufficient to fairly and completely compensate Plaintiffs and the Class for all damages, multiple or treble, as provided by law; punitive damages as provided by law; pre-judgment and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate;
- E. Award such equitable relief against Defendants as the Court should find appropriate, including disgorgement of illicit proceeds and other orders;
- F. Award Plaintiffs their cost of suit, including reasonable attorneys' fees as provided by law;
- G. Enter judgment against Defendants, jointly and severally, and in favor of Plaintiffs; and
- H. Award such further and additional relief as the Court may deem just and proper under the circumstances.

JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable.

Dated: March 11, 2019

Respectfully Submitted,

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Exhibit 16

AM. HOSP. ASS'N, HOSPITALS AND HEALTH SYSTEMS FACE UNPRECEDENTED
FINANCIAL PRESSURES DUE TO COVID-19 (May 2020),
<https://www.aha.org/system/files/media/file/2020/05/aha-covid19-financial-impact-0520-FINAL.pdf>



Hospitals and Health Systems Face Unprecedented Financial Pressures Due to COVID-19

Introduction

America's hospitals and health systems have stepped up in heroic and unprecedented ways to meet the challenges of COVID-19. As outbreaks have occurred across the country infecting more than 1 million people, hospitals have ramped up testing efforts and are treating hundreds of thousands of Americans in an effort to save lives and minimize the virus' spread.¹ This includes establishing testing tents, adding general and intensive care unit (ICU) bed capacity, and developing COVID-19 units to isolate and treat patients with the disease while safeguarding the health of other patients and hospital staff.

These challenges have created historic financial pressures for America's hospitals and health systems. Hospitals have cancelled non-emergency procedures, and many Americans are postponing care as they shelter in place to stop the spread of the virus. Treatment for COVID-19 has created incredible demand for certain medical equipment and supplies as the virus has disrupted supply chains, increasing the costs that hospitals face to treat COVID-19 patients. At the same time, COVID-19 has led to unprecedented job losses, giving way to a rise in the number of uninsured. And while doctors, nurses, and other health care workers have met the COVID-19 challenge with heroic efforts, many hospitals and health systems, especially those located in hotspot areas of the pandemic, are supporting them by providing essentials like child care, transportation, and in some cases, housing.

Hospitals and health systems face catastrophic financial challenges in light of the COVID-19 pandemic. The American Hospital Association (AHA) undertook four analyses to better understand and quantify these financial challenges. Including:

- the effect of COVID-19 hospitalizations on hospital costs;
- the effect of cancelled and forgone services, caused by COVID-19, on hospital revenue;
- the additional costs associated with purchasing needed personal protective equipment (PPE); and
- the costs of the additional support some hospitals are providing to their workers.

This report attempts to quantify these effects over the short-term, which are limited to the impacts over a four-month period from March 1, 2020 to June 30, 2020. Based on these analyses, the AHA estimates a **total four-month financial impact of \$202.6 billion** in losses for America's hospitals and health systems, or an average of **\$50.7 billion per month**.

Although the federal government moved quickly to provide relief, more help is needed. Critics have argued that hospitals were well funded prior to the COVID-19 public health emergency, however, the reality is that many hospitals were already facing financial pressures. Experts have raised concerns about low payment rates from government payers, which in part led the Congressional Budget Office to project that between 40% and 50% of hospitals could have negative margins by 2025 prior to the pandemic.^{2,3,4} Congress created a provider relief fund to support health care providers during the pandemic, but this fund is intended to stabilize providers in order to keep

their doors open, rather than fully restore compensation to pre-COVID-19 levels. Further, these funds are being distributed to all health care providers with only a portion of these funds going directly to hospitals.⁵ Other providers – such as physicians and other clinicians, laboratory and testing facilities, and durable medical equipment providers – are drawing down from health care provider relief funds as well.⁶ Hospitals and health systems will need more funds to treat patients, save lives, and get America back on its feet.

This report assesses the financial impact of COVID-19 on hospitals and health systems. It begins with an overview of the crisis and how it has affected hospitals and health systems. Then, it describes the approach used to model the impacts, including key assumptions and data sources used to complete the analysis. Then, the report presents the findings in greater detail and concludes with a discussion of these findings.

Background

In mid-January, 2020, the first case of COVID-19 in the U.S. was reported in Snohomish County, Wash.⁷ Confirmed cases increased to 1,000 by March 11, 100,000 by March 27, and over 1 million on April 28. The effect of the virus on daily life was swift and catastrophic with the advent of strict social distancing practices and stay-at-home orders. California Gov. Gavin Newsom was the first governor to issue a stay-at-home order on March 19, and by early April every state had restrictions in place to mitigate the spread of the disease.⁸

The virus has effectively grounded both local and national economies to a halt. More than 30 million Americans have filed for unemployment insurance since the end of February.⁹ The St. Louis Federal Reserve estimated that this number could rise as high as 47 million by the end of the second quarter of 2020.¹⁰ On April 29, the U.S. Department of Commerce found that first quarter gross domestic product contracted by 4.8% – an important signal of the pandemic's deleterious effects on the American economy.¹¹ These economic impacts have devastated many industries including our nation's hospitals and health systems.

Hospital and health system revenues have declined sharply as a result of the COVID-19 pandemic. To increase personal and public safety across the country while conserving PPE, hospitals moved to cancel non-emergency procedures. At the same time, many Americans have forgone care, including primary care and other specialty care visits. On March 18, the Centers for Medicare & Medicaid Services (CMS) recommended that most elective surgeries and non-essential medical, surgical and dental procedures be cancelled or delayed during the COVID-19 outbreak.¹² Since then, several governors mandated cancellation of non-essential services in their state.

These measures have resulted in adjusted discharges – a measure that accounts for both inpatient and outpatient services – decreasing by 13% from the previous year.¹³ Health care providers have raised concerns that patients are forgoing important care, such as chronic disease management, which can further jeopardize their health.¹⁴ An additional consequence of these factors has been steep reductions in revenue for all hospitals and health systems across the country.

These losses in revenue have been met with a sharp increase in costs for hospitals since the beginning of the pandemic. COVID-19 outbreaks in parts of the country have resulted in surges in hospitalizations and ICU patients. The Centers for Disease Control and Prevention estimated the cumulative hospitalization rate to be 29.2 per 100,000 people, with even higher rates for Medicare-aged individuals (95.5 per 100,000) and adults aged 50-64 (47.2 per 100,000).¹⁵ COVID-19-related hospitalizations are associated with high costs of treatment:

- The Kaiser Family Foundation estimates that the cost of treating a patient with COVID-19 could be more than \$20,000, and over \$88,000 for patients that require ventilator support.¹⁶

- A study by FAIR Health estimated the average cost of treating patients with commercial coverage to be \$38,221.¹⁷

At the same time, experts anticipate that millions of Americans could become uninsured given the spike in unemployment. The number of people without insurance could increase to over 40 million.¹⁸ These coverage losses put families at financial risk and increase uncompensated care at hospitals. Hospitals have already seen some of the effects manifest; bad debt and charity care increased 13% over the previous year in March, according to a recent study from Kaufman Hall.¹⁹

The above estimates do not include the additional costs of acquiring drugs, medical supplies and equipment that hospitals must incur to meet the demand for services. COVID-19 increased the demand for medical equipment and supplies, such as hospital beds and ventilators, and disrupted many supply chains. As a result, prices for these necessary supplies have increased exponentially since the beginning of the pandemic. For example:

- The Society for Healthcare Organization Procurement Professionals (SHOPP) estimated that costs of certain medical supplies have increased tenfold since the beginning of the pandemic.²⁰
- Hospitals in New York City reported paying four times the usual price for medical gloves and 15 times the usual price for masks.²¹

Moreover, these estimates do not account for increased labor costs. Many hospitals are experiencing increased overtime costs as hospitals experience a surge in patients or front-line workers become sick. Some hospitals have implemented bonus pay for front-line employees. Some have turned to staffing firms to address health care worker shortages or meet surge demand, and staffing firms have increased their prices due to an increase in demand for health care workers.

Supporting front-line health care workers. Physicians, nurses, and health care workers are on the frontlines of battle against the disease. Some hospitals have incurred costs to ensure that workers and their families are cared for while the workers are providing care to COVID-19 patients. For example, many health care workers need child care while they are working.²² Housing, transportation, and COVID-19 screening and testing costs have also emerged as important needs for health care workers. Hospitals and health systems are working to develop solutions that meet the needs of their employees.

Methodology

The AHA undertook four analyses to estimate the financial impact of these challenges. This includes:

- the net financial impact of COVID-19 on hospital costs;
- total revenue losses from cancelled surgeries and other services;
- the additional costs associated with purchasing needed PPE; and
- the costs of the additional support some hospitals are providing to their workers.

Below is an overview of the methodology used in these analyses. Additional detail about the methodology is found in the appendix at the end of this report.

The estimates described here are limited to the impacts over a four-month period from March 1, 2020 to June 30, 2020. This study does not assess the financial impact of continued revenue losses or increased costs beyond June 30. Any future waves of COVID-19 infections may result in additional net losses. Further, this study also does not assess the long-term, systemic financial impacts of the COVID-19 pandemic on hospitals or the communities they serve. Therefore, these estimates likely under represent the full financial losses that hospitals and health systems face.

Net Financial Impact of COVID-19 Hospitalizations

The net financial impact of COVID-19 hospitalizations was calculated by relying on a variety of data sources and recent modeling to estimate the three primary components of the model: (1) the total number of COVID-19 hospitalizations in the U.S. over a four-month period; (2) the incremental cost of a COVID-19 hospitalization; and (3) the expected reimbursement from private and government payers for COVID-19 hospitalizations.

To estimate the total number of expected hospitalizations, local COVID-19 hospitalization data to date were scaled-up to the U.S. population. Payer mix data were then applied to generate estimates of hospitalizations by payer. The incremental cost of a COVID-19 hospitalization was estimated by segmenting the hospitalizations into two cohorts – those who require mechanical ventilation and those who do not – and applying published cost estimates for clinical diagnoses most similar to COVID-19. To estimate payments received for these hospitalizations, Medicare payment data were used for the same clinical diagnoses used to estimate costs. These amounts were adjusted to include the 20% MS-DRG add-on for COVID-19 treatment. The Medicare payments were scaled to Medicaid, commercial payers, and the uninsured based on available published payment ratios. The final step was to subtract payments from costs for each payer and aggregate those net impacts to generate a total financial impact across all payers.

Total Revenue Losses from Cancelled Surgeries and Other Services

Estimates of the lost revenue from cancelled hospital services due to the COVID-19 pandemic were calculated using a combination of 2018 Medicare inpatient and outpatient claims files and the 2018 AHA Annual Survey Database (ASDB). Claims were classified into three categories: emergency department (ED)-related; non-ED-related medical; and non ED-related surgical. Medicare revenues were calculated from claims data, and revenues for other payers were estimated using ratios of net revenues from the other payers to those from Medicare, derived from the ASDB. Three different levels of service interruptions under which hospitals may operate were then identified:

- Level 1: cancellation of 67% of ED-related services; cancellation of all non ED-related services
- Level 2: cancellation of 67% of ED-related services; cancellation of 50% of non ED-related medical services; cancellation of all non ED-related surgical services
- Level 3: cancellation of 67% of ED-related services; cancellation of 50% of all non ED-related services

Finally, these levels of service interruptions were blended over a four-month timeframe to estimate the lost revenue due to cancelled services.

Additional Costs Associated with Purchasing Needed PPE

Data from SHOPP were used to estimate the increased costs of purchasing PPE. SHOPP provided estimated costs for acquiring PPE prior to the COVID-19 pandemic and the current estimated costs for acquiring PPE during the pandemic, using CDC guidelines. The difference in prices was calculated and then scaled up by the total number of U.S. hospital beds.

Costs of Additional Support Some Hospitals are Providing to their Workers

This analysis estimates the costs of providing support to front-line hospital workers located in COVID-19 hotspots and their families, including child care, housing, transportation, and COVID-19 screening and treatment. Hotspots were identified as the top 100 counties with the highest COVID-19 infection rate, using county-level data matched against the AHA ASDB.²³ Publicly available data on the daily costs of child care, daily public transportation costs, and the estimated federal per diem rates for lodging were used to generate estimates for each of these support services. Cost estimates of COVID-19 hospitalizations were used for estimating treatment costs for hospital workers infected with COVID-19 and estimates of laboratory test costs were used for the total cost of screening hospital workers for COVID-19 were aggregated to generate the total estimate of the cost hospitals are incurring in providing these support services. We assume hospitals are bearing some portion of these costs.

Results

The AHA estimates a **total four-month financial impact of \$202.6 billion** in losses for America's hospitals and health systems, or an average of **\$50.7 billion per month**. This estimate was derived by combining the estimates of various components of reduced revenue and increased costs described below.

Net Financial Impact of COVID-19 Hospitalizations

- The AHA estimates the net financial impact of COVID-19 hospitalizations over a four-month period will be \$36.6 billion. In other words, the nation's hospitals and health systems will collectively lose \$36.6 billion, including payments for COVID-19 patients, from March to June 2020 treating COVID-19 patients alone.

Total Revenue Losses from Cancelled Surgeries and Other Services

- The AHA estimates that, as a result of cancelled hospital services due to the COVID-19 pandemic, U.S. non-federal hospitals stand to lose approximately \$161.4 billion in revenue over a period of four months, from March to June 2020. This includes cancelled surgeries, various levels of cancelled non-elective surgeries and outpatient treatment, and reduced emergency department services.

Additional Costs Associated with Purchasing Needed PPE

- The AHA estimates the non-treatment costs for hospitals and health systems to be \$2.4 billion over a period of four months, from March to June 2020, or roughly \$600 million per month. Demand for equipment and supplies, such as PPE, has increased as a result of the COVID-19 pandemic. Hospitals have incurred additional costs as they struggle to acquire additional supplies to meet the needs of their patients and staff. Moreover, current guidelines require all hospital workers to wear some PPE, regardless of whether they are in direct contact with COVID-19 patients. These guidelines increase the need and expense for PPE relative to normal operations.

Costs of Additional Support Some Hospitals are Providing to their Front-line Workers

- The AHA estimates the cost of support for front-line hospital workers in COVID-19 hotspots to be \$2.2 billion through the end of June, or just under \$550 million per month. This includes the costs of providing child care, housing, transportation, and medical screening and treatment for COVID-19 for front-line workers. This estimate could increase as more outbreaks of COVID-19 occur, or if the policy decision was made to extend these benefits to all health care workers during the pandemic.

Discussion

Hospitals face catastrophic financial challenges in light of the COVID-19 pandemic. The AHA estimates a **total four-month financial impact of \$202.6 billion** in losses for America's hospitals and health systems, or an average of **\$50.7 billion per month**.

As with any model, these findings are sensitive to underlying assumptions. While the model accounts for the many costs borne by hospitals during this pandemic, there are additional costs that were not included due to limited available data. Therefore, the four-month financial impact estimate likely under-represents the true financial impact our hospitals and health systems face. Some of these important additional costs are:

- **Drug Shortage Costs.** Every year, hospitals expend financial resources to cope with ongoing drug shortages, with one estimate putting this cost at nearly \$400 million per year.²⁴ Due to the pandemic, lower than normal drug supply due to fractured pharmaceutical supply chains has been met with increasing demand for certain drugs necessary to treat the surge of patients with COVID-19 infections. This situation has created a perfect storm for drug shortages for many vital drugs resulting in higher costs for hospitals.
- **Wage and Labor Costs.** Salary and wage costs have risen during the COVID-19 pandemic. Many hospitals are experiencing increased overtime costs as hospitals experience a surge in patients or front-line workers become sick. Some hospitals have implemented bonus pay for front-line workers. Some have turned to staffing firms to address health care worker shortages or meet surge demand, and staffing firms have increased their prices due to an increase in demand for health care workers. The effect of the virus on hospital wages and labor costs is clear. However, it is not evenly distributed across the country and there are not yet reliable data that can be analyzed to understand the magnitude of the effect.
- **Non-PPE Medical Supplies and Equipment Costs.** Hospitals have experienced increased costs for non-PPE medical supplies and equipment. For example, many hospitals acquired ventilators in anticipation of a surge of COVID-19 patients. There are limited data available to understand the additional cost-burden hospitals face as they acquire non-PPE medical supplies and equipment in preparation for COVID-19 patients.
- **Capital Costs.** As the demand for hospital services has increased due to the pandemic, many hospitals and health systems around the country have worked to expand their treatment capacity by incurring costs to set up additional space for COVID-19 testing tents, ICU beds, and other treatment beds.

The totality of these costs combined with the uncertainty of the pandemic's duration is certain to imperil hospital finances. After years of declining margins, it was only recently that many of the credit rating agencies expressed optimism about hospitals' ability to weather low payment rates from government providers amidst increasing enrollment in government programs, competition from tech disruptors, and other increasing costs such as prescription drugs, and salary and wages. A third of U.S. community hospitals had negative operating margins in 2018.²⁵

Congress has moved quickly to support the country during the COVID-19 pandemic. Congress allocated \$100 billion for provider relief in the Coronavirus Aid, Relief, and Economic Security Act, and added \$75 billion to the relief fund in the Paycheck Protection Program and Health Care Enhancement Act. However, the AHA has expressed concern with how the funds have been distributed and the timeliness of these payments.²⁶

More support is needed. Hospitals continue to experience losses from cancelled and delayed procedures, while

incurring increased costs for treating patients suffering from COVID-19 and purchasing the equipment and supplies necessary to ensure the health and safety of patients, providers, and their families. Additional support will be critical as the country moves into a new phase of recovery and rebuilding. During this time, we'll need to address health disparities and ensure the health and safety of vulnerable communities. We'll face new behavioral health challenges in light of all that our nation has experienced. And we'll need increased resources to address clinical resiliency to support the health care workers who answered the call when the country needed them.

As the country faces the inimitable challenges of COVID-19 head-on, Americans cannot afford the cost of closed hospitals and restricted access to life saving treatment – action is needed urgently to support our nation's hospitals and health systems and the heroes that work there.

Appendix: Methodology

The detailed methodology used in the AHA's modeling of the net financial impact of COVID-19 to hospitals and health systems is outlined below. The AHA undertook four analyses to estimate the financial impact of these challenges:

- the net financial impact of COVID-19 on hospital costs;
- total revenue losses from cancelled surgeries and other services;
- the additional costs associated with purchasing needed PPE and other supplies; and
- the costs of the additional support some hospitals are providing to their workers.

Net Financial Impact of COVID-19 Hospitalizations

The total number of COVID-19 hospitalizations in the U.S. over a four-month period. For the first component, a nationwide estimate of COVID-19 hospitalizations was calculated using data published by the New York City Department of Health and Mental Hygiene on the total number of hospitalized COVID-19 cases in New York City to date.²⁷ The hospitalization rate was then scaled up to a national estimate using U.S. Census population estimates, converted to hospitalizations per day and then applied over the four-month period of the AHA model. To estimate COVID-19 hospitalizations by payer, a payer mix estimate was derived from a 2019 study that evaluated emergency department visits by payer using Healthcare Cost and Utilization Project (HCUP) data for pulmonary conditions (pneumonia and other similar respiratory illnesses).²⁸ Our model did not adjust for any potential changes in payer mix due to the projected increases in the uninsured, as data on the exact nature of these changes are limited and it is unclear how changes in insurance status would manifest in changes in payer mix for COVID-19 hospitalizations.

The incremental cost of a COVID-19 hospitalization. For the second component, patients were segmented into two cohorts based on available clinical data: those who require mechanical ventilation and those who do not. Because mechanical ventilation use is often a sign of significant morbidity and impending mortality, the costs associated with its use are much higher than for patients who do not require that level of treatment. Therefore, total costs of treatment were estimated separately for patients who require mechanical ventilation and those who do not based on a set of corresponding diagnosis groups (DRGs) commonly used in payment for inpatient hospital services. These separate costs were then blended based on literature suggesting that only 20% of COVID-19 hospitalizations require ventilator use.²⁹ Rather than focusing on the total cost of COVID-19 treatment, the incremental cost of a COVID-19 hospitalization was then calculated.

The expected reimbursement from private and government payers for COVID-19 hospitalizations. The third component involved estimating reimbursements for COVID-19 hospitalizations for the two cohorts of patients mentioned above. Since reimbursement data for COVID-19 are not yet publicly available, Medicare data from the FY 2020 inpatient final rule were relied on to estimate a Medicare payment amount for COVID-19 hospitalization for each cohort of patients. These amounts were adjusted to include the 20% MS-DRG add-on for COVID-19 treatment. As with the estimate of costs, Medicare payment amounts for patients requiring mechanical ventilation were blended with those who do not. This blended Medicare payment amount was scaled to commercial payers and Medicaid based on published Medicare payment ratios.^{30,31} It is unclear what the mechanism or level of payment for the uninsured will be at this time. Although the Department of Health and Human Services has announced that a portion of the \$100 billion Provider Relief Fund will be used to reimburse health care providers

who have provided treatment for uninsured COVID-19 patients on or after Feb. 4, 2020 at Medicare rates, it also stated that this would be "subject to available funding." Since it is uncertain how much funding will be available and for how long, this analysis assumes reimbursement at 50% of Medicare rates.

Finally, the net financial impact of COVID-19 hospitalizations over a four-month period for each payer was calculated by multiplying the number of hospitalizations for that payer by the estimated cost of and payment for, a COVID-19 hospitalization. The net financial impacts for each payer were then summed to generate a total net financial impact estimate.

Total Revenue Losses from Cancelled Surgeries and Other Services

Claims were classified into three categories of services: emergency department (ED)-related; non ED-related medical; and non ED-related surgical. For inpatient claims, ED-related services were identified if ED charges on the claim exceeded \$2,500: these were considered hospital inpatients that were admitted through the ED. For outpatient services, any claim with an ED charge was considered ED-related. Of the remaining non ED-related claims, inpatient services were classified as medical or surgical based on a crosswalk created by CMS that identifies Medicare severity diagnosis-related groups (MS-DRGs) as either medical or surgical. Outpatient surgical claims were identified using a range of current procedural terminology (CPT) codes for surgery of 10004 - 69990. Claims with CPT codes in the range of 36400 – 36425 (venipuncture) were not counted as surgical but instead placed in the medical service category.

Using provider net revenues for different payer types in the AHA Annual Survey Database, Medicare revenues calculated from the claims were estimated for other payers using the ratio of other payer net revenues to Medicare net revenues, and the resulting revenues were summed across providers. Furthermore, since the Medicare claims only included PPS and Maryland hospitals, total revenues across these hospitals were scaled to estimate total impacts for all hospitals in the U.S. (excluding federal hospitals).

Three levels of service interruptions were considered:

- Level 1: cancellation of 67% of ED-related services; cancellation of all non ED-related services
- Level 2: cancellation of 67% of ED-related services; cancellation of 50% of non ED-related medical services; cancellation of all non ED-related surgical services
- Level 3: cancellation of 67% of ED-related services; cancellation of 50% of all non ED-related services

This analysis uses a time period of four months, but given the uncertainty of what might happen beyond that time period, the estimated loss is most probably understated. The different levels of service interruptions over the four-month period were blended to reflect differences state-instituted moratoriums on non-ED procedures and differences in when states are easing these restrictions.

Additional Costs Associated with Purchasing Needed PPE

To estimate the increased costs of purchasing PPE, data from the Society for Healthcare Organization Procurement Professionals (SHOPP) were relied upon. SHOPP estimated the cost per day per bed for acquiring PPE "pre-COVID" (\$0.35/per bed day) and the current costs of acquiring PPE (\$25.58/ per bed day), accounting for the increase in demand and the need for more PPE based on CDC guidelines. The estimated daily costs under both

scenarios were scaled-up by the total number of U.S. hospital beds (excluding federal hospitals) and scaled up to generate monthly estimated totals.

Costs of Additional Support Some Hospitals are Providing to their Workers

This analysis estimates the costs of providing support to front-line hospital workers and their families, including child care, housing, transportation, and COVID-19 screening and treatment. While hospitals and health systems around the country are providing these supports to their front-line workers, it is especially the case for hospitals located in areas deemed as “hotspots” for COVID-19. Hotspots were identified as the top 100 counties with the highest COVID-19 infection rate, using county-level data matched against the AHA ASDB.³² To be conservative in estimating national costs, these costs were calculated assuming these support services were being offered at 50% of hospitals and health systems located in these COVID-19 hotspot areas.

For child care services, the number of hospital workers located in hotspots that had children under the age of 12 that may require child care were estimated and multiplied that by the average hourly cost of child care as estimated by the Office of Planning, Research & Evaluation at the Department of Health and Human Services.³³

For transportation services, 21.3% of hospital workers in hotspots were estimated to commute using public transportation based on data from the American Community Survey and multiplied that by the average daily cost of public transportation as estimated by the Bureau of Transportation Services.³⁴

For the cost of providing housing, 5% of hospital workers were estimated to require housing services and multiplied by the average per diem lodging rates published by the General Services Administration.³⁵

To estimate the costs of providing free daily testing for COVID-19, lab cost estimates (\$120/test) by Covered California were used, and multiplied by CDC estimates of the number of all COVID-19 cases among health care workers (11%), based on current testing capacity data.³⁶ Finally, to estimate the cost of covering hospitalization for hospital workers with COVID-19, CDC data for the number of hospital workers infected with COVID-19 in the U.S. were used, and the model assumes that 20% of all COVID-19 infections of hospital workers would require hospitalization. The COVID-19 hospitalization cost estimate was applied and multiplied by the number of estimated hospital workers requiring hospitalization.

Sources

1. The Johns Hopkins University (2020). COVID-19 Dashboard, accessed on April 29, 2020. Available at: <https://www.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6>.
2. Moody's Investor Service (2019). "Medians - Revenue growth rate inches ahead of expenses as margins hold steady." Accessed on April 29, 2020 at https://www.moody's.com/researchdocumentcontentpage.aspx?docid=PBM_1190409.
3. The American Hospital Association (2020). "Fact Sheet: Underpayment by Medicare and Medicaid." Accessed on April 29, 2020 at <https://www.aha.org/fact-sheets/2020-01-07-fact-sheet-underpayment-medicare-and-medicaid>
4. Congressional Budget Office (2016). "Projecting Hospitals' Profit Margins Under Several Illustrative Scenarios." Available at <https://www.cbo.gov/publication/51919>.
5. The Provider Relief Fund includes \$100 billion appropriated in the Coronavirus Aid, Relief, and Economic Security Act (CARES Act, P.L. 116-136) and \$75 billion added in the Paycheck Protection Program and Health Care Enhancement Act (P.L. 116-139).
6. U.S. Department of Health and Human Services (2020). CARES Act Provider Relief Fund. Available at: <https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/index.html>.
7. Holshue, M. et al. 2020. "First case of 2019 novel coronavirus in the United States." New England Journal of Medicine. Available at <https://www.nejm.org/doi/full/10.1056/NEJMoa2001191>.
8. The Henry J. Kaiser Family Foundation (2020). When Stay-at-Home orders due to coronavirus went into effect. Available at: <https://www.kff.org/other/slide/when-state-stay-at-home-orders-due-to-coronavirus-went-into-effect/>.
9. CNN (2020). "30 million Americans have filed initial unemployment claims since mid-March." Available at: <https://www.cnn.com/2020/04/30/economy/unemployment-benefits-coronavirus/index.html>.
10. Faria-e-Castro, M. (2020). "Back-of-the-Envelope Estimates of Next Quarter's Unemployment Rate". Federal Reserve Bank of St. Louis. Available at: <https://www.stlouisfed.org/on-the-economy/2020/march/back-envelope-estimates-next-quarters-unemployment-rate>.
11. U.S. Department of Commerce (2020). Statement from U.S. Secretary of Commerce Wilbur Ross on Q1 2020 GDP Advance Estimate. Available at: <https://www.commerce.gov/news/press-releases/2020/04/statement-us-secretary-commerce-wilbur-ross-q1-2020-gdp-advance>.
12. The Centers for Medicare & Medicaid Services (2020). CMS Releases Recommendations on Adult Elective Surgeries, Non-Essential Medical, Surgical, and Dental Procedures During COVID-19 Response. Available at: <https://www.cms.gov/newsroom/press-releases/cms-releases-recommendations-adult-elective-surgeries-non-essential-medical-surgical-and-dental>.
13. Kaufman Hall (2020). "National Hospital Flash Report, April 2020."
14. So-called elective procedures are not considered optional surgeries, but non-emergent. These procedures can alleviate pain, improve quality of life and be otherwise life changing for patients. For some, delaying care could create additional complications later. It remains to be seen what the long-term effects are of delaying care as a result of COVID-19, both in terms of costs for individuals and hospitals, and in terms of health outcomes.
15. The Centers for Disease Control (2020). COVIDView: A weekly surveillance summary of U.S. COVID-19 activity. Updated April 24, 2020. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html>.
16. Rae, M. et al. (2020). "Potential costs of COVID-19 treatment for people with employer coverage." Available at: <https://www.healthsystemtracker.org/brief/potential-costs-of-coronavirus-treatment-for-people-with-employer-coverage/>.
17. FAIR Health, Inc. (2020). COVID-19: The projected economic impact of the COVID-19 pandemic on the US healthcare system. Available at: <https://s3.amazonaws.com/media2.fairhealth.org/brief/asset/COVID-19%20-%20The%20Projected%20Economic%20Impact%20of%20the%20COVID-19%20Pandemic%20on%20the%20US%20Healthcare%20System.pdf>.
18. Health Management Associates (2020). COVID-19 Impact on Medicaid, Marketplace, and the Uninsured, by State. Available at: <https://www.healthmanagement.com/wp-content/uploads/HMA-Estimates-of-COVID-Impact-on-Coverage-public-version-for-April-3-830-CT.pdf>.
19. Kaufman Hall (2020). "National Hospital Flash Report, April 2020."
20. The Society for Healthcare Organization Procurement Professionals (2020). White paper re: Marginal PPE costs incurred by skilled nursing facilities and assisted living centers treating COVID-19 patients. Available at: http://cdn.cnn.com/cnn/2020/images/04/16/shopp.covid.ppd.costs.analysis_.pdf.
21. DePillis, L., and L. Song (2020). "In Desperation, New York State Pays Up to 15 Times the Normal Prices for Medical Equipment." ProPublica. Available at: <https://www.propublica.org/article/in-desperation-new-york-state-pays-up-to-15-times-the-normal-price-for-medical-equipment>.
22. Fetter, A. (2020). "The Child-Care Crisis Is Even Worse for Health-Care Workers." The Atlantic. Available at: <https://www.theatlantic.com/family/archive/2020/03/who-is-taking-care-of-hospital-workers-children/608848/>.
23. The Johns Hopkins University (2020). COVID-19 Dashboard, accessed on April 29, 2020. Available at: <https://www.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6>.
24. Vizient, Inc. (2020). "Essential medications for patient care." Available at: <https://www.vizientinc.com/our-solutions/pharmacy-solutions/drug-shortages>.
25. American Hospital Association analysis of AHA Annual Survey Database. April 29, 2020.
26. The American Hospital Association (2020). Letter to the Honorable Alex M. Azar, Secretary of U.S. Department of Health and Human Services. <https://www.aha.org/system/files/media/file/2020/04/aha-expresses-concern-with-hhs-distribution-of-emergency-funds-4-27-2020.pdf>.
27. City of New York (2020). Coronavirus disease 2019 (COVID-19): Daily data summary for April 19, 2020. Available at: <https://www1.nyc.gov/assets/doh/downloads/pdf/imm/covid-19-daily-data-summary-hospitalizations-04202020-1.pdf>.
28. Venkatesh, A. K., et al. (2019). "Association between insurance status and access to hospital care in emergency department disposition." The New England Journal of Medicine. Available at: <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2729391>.
29. The World Health Organization. (2020). "Clinical management of severe acute respiratory infection (SARI) when COVID-19 disease is suspected: Interim guidance." Available at: <https://www.who.int/docs/default-source/coronavirus/clinical-management-of-novel-cov.pdf>.
30. Maeda, J. L. and L. Nelson (2017). "An analysis of hospital prices for commercial and Medicare Advantage plans." Presentation at the 2017 AcademyHealth Annual Research Meeting. Available at: <https://www.cbo.gov/system/files/115th-congress-2017-2018/presentation/52819-presentation.pdf>.
31. The Medicaid and CHIP Payment and Access Commission. "Medicaid hospital payment: A comparison across states and to Medicare." Available at: <https://www.macpac.gov/wp-content/uploads/2017/04/Medicaid-Hospital-Payment-A-Comparison-across-States-and-to-Medicare.pdf>.
32. The Johns Hopkins University (2020). COVID-19 Dashboard, accessed on April 29, 2020. Available at: <https://www.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6>.
33. The U.S. Department of Health and Human Services, Office of Planning, Research and Evaluation (2015). "Prices charged in early care and education: Initial findings from the National Survey of Early Care and Education (NSECE)." Available at: https://www.acf.hhs.gov/sites/default/files/opre/es_price_of_care_toopre_041715_2.pdf.
34. The U.S. Department of Transportation, Bureau of Transportation Statistics (2020). Average passenger fares. Available at: <https://www.bts.gov/content/average-passenger-fares-current-dollars>.
35. The U.S. General Services Administration. Per diem rates: FY 2020 per diem highlights. Available at: <https://www.gsa.gov/travel/plan-book/per-diem-rates/fy-2020-per-diem-highlights>.
36. The Centers for Disease Control and Prevention (2020). "Characteristics of Health Care Personnel with COVID-19 – United States, February 12-April 9, 2020." Morbidity and Mortality Weekly Report (MMWR). Available at: https://www.cdc.gov/mmwr/volumes/69/wr/mm6915e6.htm?s_cid=mm6915e6_w.

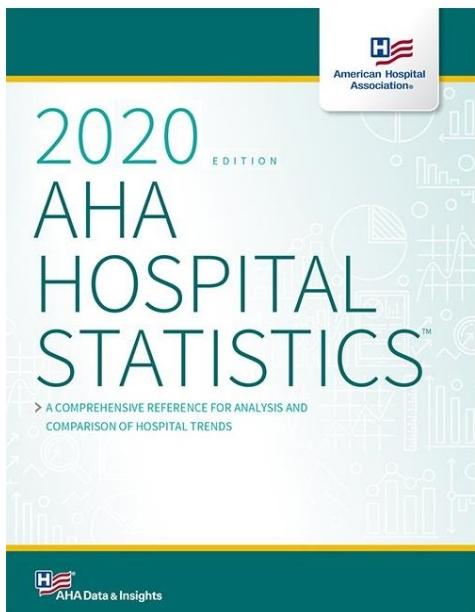
Exhibit 17

American Hospital Association, *Fast Facts on U.S. Hospitals*, AM. HOSP. ASS'N (Jan. 2020),
<https://www.aha.org/system/files/media/file/2020/01/2020-aha-hospital-fast-facts-new-Jan-2020.pdf>



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Fast Facts on US Hospitals

The American Hospital Association conducts an annual survey of hospitals in the United States. The data below, from the fiscal year 2018 AHA Annual Survey, are a sample of what you will find in *AHA Hospital Statistics*, 2020 edition. The definitive source for aggregate hospital data and trend analysis, *AHA Hospital Statistics* includes current and historical data on utilization, personnel, revenue, expenses, community health indicators, physician models, and much more.

AHA Hospital Statistics is published annually by Health Forum, an affiliate of the American Hospital Association. To order print copies of *AHA Hospital Statistics*, call (800) AHA-2626 or visit the [AHA online store](#). An [interactive online version](#) is also available. Subscribers can access [online](#).

Note that the ICU bed data is not published in *AHA Hospital Statistics*.

For further information, contact the AHA Resource Center at (312) 422-2050 or rc@aha.org

Total Number of All U.S. Hospitals	6,146
Number of U.S. Community ¹ Hospitals	5,198
Number of Nongovernment Not-for-Profit Community Hospitals	2,937
Number of Investor-Owned (For-Profit) Community Hospitals	1,296
Number of State and Local Government Community Hospitals	965
Number of Federal Government Hospitals	209
Number of Nonfederal Psychiatric Hospitals	616
Other ² Hospitals	123
Total Staffed Beds in All U.S. Hospitals	924,107
Staffed Beds in Community Hospitals	792,417
Intensive Care Beds ³ in Community Hospitals	
Medical-Surgical Intensive Care ⁴ Beds in Community Hospitals	46,825
Cardiac Intensive Care ⁵ Beds in Community Hospitals	14,439
Neonatal Intensive Care ⁶ Beds in Community Hospitals	22,860
Pediatric Intensive Care ⁷ Beds in Community Hospitals	5,131
Burn Care Beds ⁸ in Community Hospitals	1,198
Other Intensive Care ⁹ Beds in Community Hospitals	7,323
Total Admissions in All U.S. Hospitals	36,353,946
Admissions in Community Hospitals	34,251,159
Total Expenses for All U.S. Hospitals	\$1,112,207,387,000
Expenses for Community Hospitals	\$1,010,271,112,000
Number of Rural Community Hospitals	1,821
Number of Urban Community Hospitals	3,377
Number of Community Hospitals in a System ¹⁰	3,491

¹Community hospitals are defined as all nonfederal, short-term general, and other special hospitals. Other special hospitals include obstetrics and gynecology; eye, ear, nose, and throat; long term acute-care; rehabilitation; orthopedic; and other individually described specialty services. Community hospitals include academic medical centers or other teaching hospitals if they are nonfederal short-term hospitals. Excluded are hospitals not accessible by the general public, such as prison hospitals or college infirmaries.

²Other hospitals include nonfederal long term care hospitals and hospital units within an institution such as a prison hospital or school infirmary. Long term care hospitals may be defined by different methods; here they include other hospitals with an average length of stay of 30 or more days.

³Note that intensive care bed counts reflect only those hospitals that responded to the Facilities and Services of the AHA Annual Survey. In 2018, approximately 80% of hospitals responded to this section. Therefore, these responses may not be complete. Intensive care bed counts are also reported in the CMS Healthcare Cost Report Information System (HCRIS) and may be more comprehensive. Total intensive care beds are not summed because the care provided is specialized.

⁴Medical-surgical intensive care. Provides patient care of a more intensive nature than the usual medical and surgical care, on the basis of physicians' orders and approved nursing care plans. These units are staffed with specially trained nursing personnel and contain monitoring and specialized support equipment for patients who because of shock, trauma or other life-threatening conditions require intensified comprehensive observation and care. Includes mixed intensive care units.

⁵Cardiac intensive care. Provides patient care of a more specialized nature than the usual medical and surgical care, on the basis of physicians' orders and approved nursing care plans. The unit is staffed with specially trained nursing personnel and contains monitoring and specialized support or treatment equipment for patients who, because of heart seizure, open-heart surgery, or other life-threatening conditions, require intensified, comprehensive observation and care. May include myocardial infarction, pulmonary care, and heart transplant units.

⁶Neonatal intensive care. A unit that must be separate from the newborn nursery providing intensive care to all sick infants including those with the very lowest birth weights (less than 1500 grams). NICU has potential for providing mechanical ventilation, neonatal surgery, and special care for the sickest infants born in the hospital or transferred from another institution. A full-time neonatologist serves as director of the NICU.

⁷Pediatric intensive care. Provides care to pediatric patients that is of a more intensive nature than that usually provided to pediatric patients. The unit is staffed with specially trained personnel and contains monitoring and specialized support equipment for treatment of patients who, because of shock, trauma, or other life-threatening conditions, require intensified, comprehensive observation and care.

⁸Burn care. Provides care to severely burned patients. Severely burned patients are those with any of the following: (1) second-degree burns of more than 25% total body surface area for adults or 20% total body surface area for children; (2) third-degree burns of more than 10% total body surface area; (3) any severe burns of the hands, face, eyes, ears, or feet; or (4) all inhalation injuries, electrical

burns, complicated burn injuries involving fractures and other major traumas, and all other poor risk factors.

⁹Other intensive care. A specially staffed, specialty equipped, separate section of a hospital dedicated to the observation, care, and treatment of patients with life-threatening illnesses, injuries, or complications from which recovery is possible. It provides special expertise and facilities for the support of vital function and utilizes the skill of medical nursing and other staff experienced in the management of these problems.

¹⁰System is defined by AHA as either a multihospital or a diversified single hospital system. A multihospital system is two or more hospitals owned, leased, sponsored, or contract managed by a central organization. Single, freestanding hospitals may be categorized as a system by bringing into membership three or more, and at least 25 percent, of their owned or leased non-hospital preacute or postacute health care organizations.

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Updated March 2020

Exhibit 18

Ayla Ellison, *42 Hospitals Closed, Filed for Bankruptcy This Year*,
BECKER'S HEALTHCARE (June 22, 2020),
<https://www.beckershospitalreview.com/finance/42-hospitals-closed-filed-for-bankruptcy-this-year.html>

42 hospitals closed, filed for bankruptcy this year

Ayla Ellison ([Twitter](#)) - Monday, June 22nd, 2020 [Print](#) | [Email](#)

From reimbursement landscape challenges to dwindling patient volumes, many factors lead hospitals to shut down or file for bankruptcy. At least 42 hospitals across the U.S. have closed or entered bankruptcy this year, and the financial challenges caused by the COVID-19 pandemic may force more hospitals to do the same in coming months.

COVID-19 has created a cash crunch for many hospitals across the nation. They're estimated to lose \$200 billion between March 1 and June 30, according to a [report](#) from the American Hospital Association. More than \$161 billion of the expected revenue losses will come from canceled services, including nonelective surgeries and outpatient treatment. Moody's Investors Service said the sharp [declines](#) in revenue and cash flow caused by the suspension of elective procedures could cause more hospitals to default on their credit agreements this year than in 2019.

Below are the provider organizations that have filed for bankruptcy or closed since Jan. 1, beginning with the most recent. They own and operate a combined 42 hospitals.

Our Lady of Bellefonte Hospital (Ashland, Ky.)

Bon Secours Mercy Health [closed](#) Our Lady of Bellefonte Hospital in Ashland, Ky., on April 30. The 214-bed hospital was originally slated to shut down in September of this year, but the timeline was moved up after employees began accepting new jobs or tendering resignations. Bon Secours cited local competition as one reason for the hospital closure. Despite efforts to help sustain hospital operations, Bon Secours was unable to "effectively operate in an environment that has multiple acute care facilities competing for the same patients, providers and services," the health system said.

Williamson (W.Va.) Hospital

Williamson Hospital filed for Chapter 11 bankruptcy in October and was operating on thin margins for months before [shutting down](#) on April 21. The 76-bed hospital said a drop in patient volume due to the COVID-19 pandemic forced it to close. CEO Gene Preston said the decline in patient volume was "too sudden and severe" for the hospital to sustain operations.

Decatur County General Hospital (Parsons, Tenn.)

Decatur County General Hospital [closed](#) April 15, a few weeks after the local hospital board voted to shut it down. Decatur County Mayor Mike Creasy said the closure was attributable to a few factors, including rising costs, Tennessee's lack of Medicaid expansion and broader financial challenges facing the rural healthcare system in the U.S.

Quorum Health (Brentwood, Tenn.)

Quorum Health and its 23 hospitals [filed](#) for Chapter 11 bankruptcy April 7. The company, a spinoff of Franklin, Tenn.-based Community Health Systems, said the bankruptcy filing is part of a plan to recapitalize the business and reduce its debt load.

UPMC Susquehanna Sunbury (Pa.)

UPMC Susquehanna Sunbury [closed](#) March 31. Pittsburgh-based UPMC announced plans in December to close the rural hospital, citing dwindling patient volumes. Sunbury's population was 9,905 at the 2010 census, down more than 6 percent from 10 years earlier. Though the hospital officially closed its doors in March, it shut down its emergency department and ended inpatient services Jan. 31.

Fairmont (W.Va.) Regional Medical Center

Irvine, Calif.-based Alecto Healthcare Services [closed](#) Fairmont Regional Medical Center on March 19. Alecto announced plans in February to close the 207-bed hospital, citing financial challenges. "Our plans to reorganize

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some administrative functions and develop other revenue sources were insufficient to stop the financial losses at FRMC," Fairmont Regional CEO Bob Adcock said. "Our efforts to find a buyer or new source of financing were unsuccessful." Morgantown-based West Virginia University Medicine will [open](#) a 10-bed hospital with an emergency department at the former Fairmont Regional Medical Center by the end of June.

Sumner Community Hospital (Wellington, Kan.)

Sumner Community Hospital [closed](#) March 12 without providing notice to employees or the local community. Kansas City, Mo.-based Rural Hospital Group, which acquired the hospital in 2018, cited financial difficulties and lack of support from local physicians as reasons for the closure. "Lack of support from the local medical community was the primary reason we are having to close the hospital," RHG said. "We regret having to make this decision; however, despite operating the hospital in the most fiscally responsible manner possible, we simply could not overcome the divide that has existed from the time we purchased the hospital until today."

Randolph Health

Randolph Health, a single-hospital system based in Asheboro, N.C., [filed](#) for Chapter 11 bankruptcy March 6. Randolph Health leaders have taken several steps in recent years to improve the health system's financial picture, and they've made progress toward that goal. Entering Chapter 11 bankruptcy will allow Randolph Health to restructure its debt, which officials said is necessary to ensure the health system continues to provide care for many more years.

Pickens County Medical Center (Carrollton, Ala.)

Pickens County Medical Center [closed](#) March 6. Hospital leaders said the closure was attributable to the hospital's unsustainable financial position. A news release announcing the closure specifically cited reduced federal funding, lower reimbursement from commercial payers and declining patient visits.

The Medical Center at Elizabeth Place (Dayton, Ohio)

The Medical Center at Elizabeth Place, a 12-bed hospital owned by physicians in Dayton, Ohio, [closed](#) March 5. The closure came after years of financial problems. In January 2019, the Medical Center at Elizabeth Place lost its certification as a hospital, meaning it couldn't bill Medicare or Medicaid for services. Sixty to 65 percent of the hospital's patients were covered through the federal programs.

Mayo Clinic Health System-Springfield (Minn.)

Mayo Clinic Health System [closed](#) its hospital in Springfield, Minn., on March 1. Mayo announced plans in December to close the hospital and its clinics in Springfield and Lamberton, Minn. At that time, James Hebl, MD, regional vice president of Mayo Clinic Health System, said the facilities faced staffing challenges, dwindling patient volumes and other issues. The hospital in Springfield is one of eight hospitals within a less than 40-mile radius, which has led to declining admissions and low use of the emergency department, Dr. Hebl said.

Faith Community Health System

Faith Community Health System, a single-hospital system based in Jacksboro, Texas and part of the Jack County (Texas) Hospital District, first [entered](#) Chapter 9 bankruptcy — a bankruptcy proceeding that offers distressed municipalities protection from creditors while a repayment plan is negotiated — in February. The bankruptcy court dismissed the case May 26 at the request of the health system. The health system asked the court to dismiss the bankruptcy case to allow it to apply for a Paycheck Protection Program loan through a Small Business Association lender. On June 11, Faith Community Health System [reentered](#) Chapter 9 bankruptcy.

Pinnacle Healthcare System

Overland Park, Kan.-based Pinnacle Healthcare System and its hospitals in Missouri and Kansas [filed](#) for Chapter 11 bankruptcy on Feb. 12. Pinnacle Regional Hospital in Boonville, Mo., formerly known as Cooper County Memorial Hospital, entered bankruptcy about a month after it abruptly [shut down](#). Pinnacle Regional Hospital in Overland Park, formerly called Blue Valley Hospital, [closed](#) about two months after entering bankruptcy.

Central Hospital of Bowie (Texas)

Central Hospital of Bowie abruptly [closed](#) Feb. 4. Hospital officials said the facility was shut down to enable them to restructure the business. Hospital leaders voluntarily surrendered the license for Central Hospital of Bowie.

Ellwood City (Pa.) Medical Center

Ellwood City Medical Center officially [closed](#) Jan. 31. The hospital was operating under a provisional license in November when the Pennsylvania Department of Health ordered it to suspend inpatient and emergency services due to serious violations, including failure to pay employees and the inability to offer surgical services. The hospital's owner, Americore Health, suspended all clinical services at Ellwood City Medical Center Dec. 10. At that time, hospital officials said they hoped to reopen the facility in January. Plans to reopen were halted Jan. 3 after the health department conducted an onsite inspection and determined the hospital "had not shown its suitability to resume providing any health care services."

Thomas Health (South Charleston, W.Va.)

Thomas Health and its two hospitals [filed](#) for Chapter 11 bankruptcy on Jan. 10. In an affidavit filed in the bankruptcy case, Thomas Health President and CEO Daniel J. Lauffer cited several reasons the health system is facing financial challenges, including reduced reimbursement rates and patient outmigration. The health system [announced](#) June 18 that it reached an agreement in principle with a new capital partner that would allow it to emerge from bankruptcy.

St. Vincent Medical Center (Los Angeles)

St. Vincent Medical Center [closed](#) in January, roughly three weeks after El Segundo, Calif.-based Verity Health announced plans to shut down the 366-bed hospital. Verity, a nonprofit health system that entered Chapter 11 bankruptcy in 2018, shut down St. Vincent after a deal to sell four of its hospitals fell through. In April, Patrick Soon-Shiong, MD, the billionaire owner of the Los Angeles Times, purchased St. Vincent out of bankruptcy for \$135 million.

Astria Regional Medical Center (Yakima, Wash.)

Astria Regional Medical Center filed for Chapter 11 bankruptcy in May 2019 and [closed](#) in January. When the hospital closed, 463 employees lost their jobs. Attorneys representing Astria Health said the closure of Astria Regional Medical Center, which has lost \$40 million since 2017, puts Astria Health in a better financial position. "As a result of the closure ... the rest of the system's cash flows will be sufficient to safely operate patient care operations and facilities and maintain administrative solvency of the estate," states a status report filed Jan. 20 with the bankruptcy court.

More articles on healthcare finance:

[10 latest hospital credit rating downgrades](#)

[Cleveland Clinic cancels raises, faces \\$500M revenue shortfall](#)

[Private equity pushes into healthcare: 8 latest deals](#)

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Exhibit 19

Centers for Disease Control and Prevention, *Prescription Opioid Data*,
<https://www.cdc.gov/drugoverdose/data/prescribing.html> (last visited June 25, 2020)



Opioid Overdose

Overview

Millions of Americans suffer from pain and are often prescribed opioids to treat their conditions. However, the dangers of prescription misuse, opioid use disorder, and overdose have been a growing problem throughout the United States.

Since the 1990s, when the amount of opioids prescribed to patients began to grow, the number of overdoses and deaths from prescription opioids has also increased. Even as the amount of opioids prescribed and sold for pain has increased, the amount of pain that Americans report has not similarly changed.

From 1999 to 2018, more than 232,000 people died in the United States from overdoses involving prescription opioids. Overdose deaths involving prescription opioids were more than four times higher in 2018 than in 1999.¹



More than 232,000 Americans have lost their lives to overdoses involving prescription opioids from 1999–2018.

References

1. Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2020. Available at <http://wonder.cdc.gov>.

Page last reviewed: March 19, 2020, 12:00 AM

Exhibit 20

The Editorial Board, *An Opioid Crisis Foretold*, N.Y. TIMES (Apr. 21, 2018),
<https://www.nytimes.com/2018/04/21/opinion/an-opioid-crisis-foretold.html>

EDITORIAL

An Opioid Crisis Foretold

By The Editorial Board

The editorial board represents the opinions of the board, its editor and the publisher.
It is separate from the newsroom and the Op-Ed section.

April 21, 2018

One of the more distressing truths of America's opioid epidemic, which now kills tens of thousands of people every year, is that it isn't the first such crisis. Across the 19th and 20th centuries, the United States, China and other countries saw drug abuse surge as opium and morphine were used widely as recreational drugs and medicine. In the West, doctors administered morphine liberally to their patients, while families used laudanum, an opium tincture, as a cure-all, including for pacifying colicky children. In China, many millions of people were hooked on smoking opium. In the mid-1800s, the British went into battle twice — bombing forts and killing thousands of civilians and soldiers alike — to keep the Chinese market open to drug imports in what would become known as the Opium Wars.



Victims in the second Opium War, circa 1860.
Hulton-Deutsch Collection/Corbis, via Getty Images

That history has either been forgotten or willfully ignored by many in the medical and political establishments.

Today's opioid crisis is already the deadliest drug epidemic in American history. Opioid overdoses killed more than 45,000 people in the 12 months that ended in September, according to the Centers for Disease Control and Prevention. The epidemic is now responsible for nearly as many American deaths per year as AIDS was at the peak of that crisis.

Experts say that the death toll from opioids could climb for years to come. Millions of people are dependent on or addicted to these drugs, and many of them are increasingly turning to more potent, illicit supplies of heroin and fentanyl, which are cheap and readily available on the street and online. Yet only about 10 percent of Americans who suffer from substance abuse receive specialized addiction treatment, according to a report by the surgeon general.

WE HAVE SEEN THIS BEFORE

As many as 313,000 people were addicted to injected morphine and smoked opium in the United States in the late 19th century, according to David Courtwright, a history professor at the University of North Florida who has written extensively about drugs. Another scholar, R. K. Newman, estimated that as many as 16.2 million Chinese were dependent on opium and smoked the drug daily.



Opium smokers in China, circa 1880. Corbis, via Getty Images

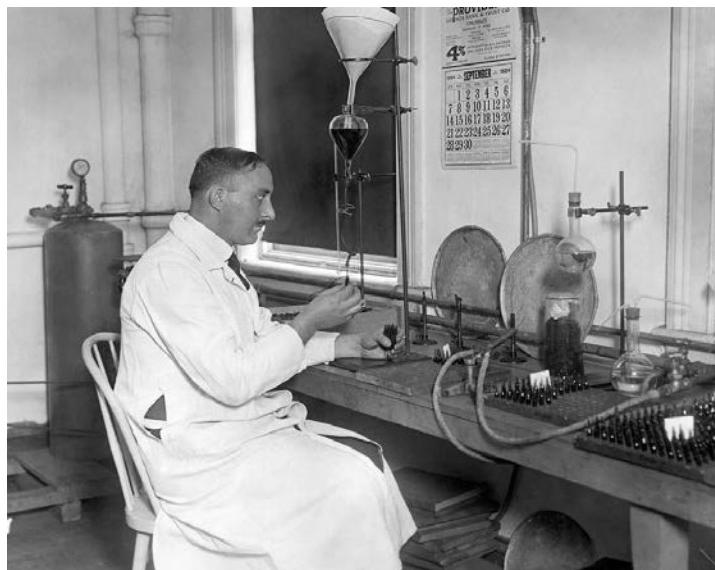
In the United States today, about 2.6 million people suffer from opioid use disorder. But some experts say that data, which is based on a government survey, underestimates the number of pain patients who are addicted to their prescription pills because of how surveyors ask people about drug use; the actual number might exceed five million.

In the 19th century, like today, the medical community was largely responsible for the epidemic. Doctors did not fully appreciate the risks these drugs posed. In the 1800s, many doctors viewed morphine as a wonder drug for pain, diarrhea, nerves and alcoholism. In addition to getting homemakers, Civil War veterans and others addicted, many doctors became addicts themselves. The drug was overused in large part because there were few alternatives; aspirin, for example, didn't become available until the late 1890s.



A magazine advertisement promoting heroin and aspirin, circa 1900. Bettmann Archive/Getty Images

In his 2001 book, "Dark Paradise: A History of Opiate Addiction in America," Mr. Courtwright notes that the use of morphine began declining as younger doctors who had been better trained started practicing medicine and as non-addictive pain treatments became available. He also notes that many local governments across the country set up clinics that sought to help addicts — a forerunner of contemporary methadone clinics — but a hostile federal government forced virtually all of them to shut down by 1923. It did so under the misguided idea that it was wrong to keep supplying drugs to people who had become dependent on them — a view that is, regrettably, still widespread today.



A technician working on treatments for heroin and morphine addiction in 1924. Underwood Archives/Getty Images

Today's opioid crisis has its roots in the 1990s, when prescriptions for painkillers like OxyContin and Vicodin started to become common. Companies like Purdue Pharma, which makes OxyContin, aggressively peddled the idea that these drugs were not addictive with the help of dubious or misinterpreted research. One short 1980 letter to The New England Journal of Medicine by Dr. Hershel Jick and Jane Porter said the risk of addiction was less than one percent, based on an analysis of nearly 12,000 hospital patients who were given opioid painkillers. That letter was widely — and incorrectly — cited as evidence that opioids were safe.

Federal regulators, doctors and others were swayed by pharmaceutical companies that argued for greater use of opioids; there was increasing awareness that doctors had become too unresponsive to patients who were in pain. Patient advocates and pain specialists demanded that the medical establishment recognize pain as the "fifth vital sign."

Mr. Courtwright says that this was not a simple case of historical amnesia. In the earlier epidemic, doctors "made mistakes, but it was a bad situation to begin with," he said. "There was no equivalent of Purdue Pharma flying you off to the Bahamas for the weekend to tell you about the wonders of these new drugs."

WHAT SHOULD WE DO NOW?

The AIDS crisis might provide public officials some lessons for how to move forward. Like with opioids, the federal government responded to that epidemic by doing next to nothing for many years. But an organized movement led in part by people with H.I.V. and gay activists eventually forced Congress to create and fund new programs. For example, in 1990 Congress approved the Ryan White Care Act, a bipartisan bill that poured billions of dollars into providing treatment and support to people with H.I.V. By 1995, the federal government was spending \$3.3 billion a year (about \$5.4 billion today after adjusting for inflation) on AIDS efforts, not including billions spent through mandatory programs like Medicaid and Medicare, according to the Kaiser Family Foundation. That was up from just \$116 million in 1985.

Though slow to act, Congress eventually treated AIDS as a complex, multidimensional problem and tackled it by funding prevention, treatment, support services and research. Lawmakers provided money to make expensive antiretroviral drugs accessible to more people and allocated money to help house people infected with H.I.V., recognizing that they needed more than just access to drugs.



AIDS activists demonstrating in New York in 1988.
Allan Tannenbaum/Getty Images

Lawmakers so far have fallen far short of such a vigorous effort when it comes to opioid addiction. Congress has taken what can be considered only baby steps by appropriating a total of a few billion dollars of discretionary opioid funding in recent years. This funding amounts to a pittance relative to what is needed: substantial long-term funding for prevention, addiction treatment, social services and research. Andrew Kolodny, co-director of opioid policy research at Brandeis University, says at least \$6 billion a year is needed for 10 years to set up a nationwide network of clinics and doctors to provide treatment with medicines like buprenorphine and methadone. Those drugs have a proven track record at reducing overdoses and giving people struggling with addiction a shot at a stable life. Today, large parts of the country have few or no clinics that offer medication-assisted treatment, according to an analysis by amfAR, a foundation that funds AIDS research.

Next, lawmakers need to remove regulations restricting access to buprenorphine, an opioid that can be used to get people off stronger drugs like heroin; its use is unlikely to end in an overdose. Doctors who want to prescribe the drug have to go through eight hours of training, and the government limits the number of patients they can treat. These limits have made the drug harder to obtain and created a situation in which it is easier to get the kinds of opioids that caused this crisis than to get medicine that can help addicts. France reduced heroin overdoses by nearly 80 percent by making buprenorphine easily available starting in 1995. Yet many American lawmakers and government officials have resisted removing restrictions on buprenorphine, arguing it replaces one addiction with another. Some of the same people have also stood in the way of wider availability of naloxone, which can help reverse overdoses, and opposed harm-reduction approaches like supervised drug consumption sites, where users can get clean needles and use drugs under the watch of staff who are trained to reverse overdoses.

To stem the number of new opioid users, lawmakers and regulators need to stop pharmaceutical companies from marketing drugs like OxyContin and establish stronger guidelines about how and when doctors can prescribe them. These drugs are often the last resort for people with cancer and other terminal conditions who experience excruciating pain. But they pose a great risk when used to treat the kinds of pain for which there are numerous nonaddictive therapies available. Doctors have been writing fewer opioid prescriptions in recent years, but even the new level is too high.

Some lawmakers have begun to take this epidemic seriously. Senator Elizabeth Warren and Representative Elijah Cummings, both Democrats, recently proposed legislation modeled on the Ryan White Act that would appropriate \$100 billion over 10 years for research, treatment and support. While that might seem like a lot, President Trump's Council of Economic Advisers said in November that the epidemic cost the economy \$504 billion in 2015 alone.

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Leaders in both parties are responsible for this crisis. Presidents George W. Bush and Barack Obama and members of Congress did too little to stop it in its earlier stages. While Mr. Trump talks a lot about the problem, he seems to have few good ideas for what to do about it. As we've learned the hard way, without stronger leadership, the opioid epidemic will continue to wreak havoc across the country.